



POST GRADUATE MEDICAL EDUCATION  
DEPARTMENT  
**KHYBER GIRLS MEDICAL COLLEGE**  
BLOCK -IV, PDA BUILDING, PHASE-V, HAYATABAD,  
KHYBER PAKHTUNKHWA, PESHAWAR, PAKISTAN  
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APPLICATION FORM FOR SUBMISSION OF RESEARCH PROPOSALS TO KMU-AS&RB

Serial No (for office use): \_\_\_\_\_

Date of submission: 22/01/2018

Name of the Institute: Khyber Girls Medical College Hayatabad Peshawar, Post Graduate Medical Education Department.

Date of Registration with institute: 17<sup>th</sup> September 2015 Session: 2015-17

Program/Specialty: M.Phil / Chemical Pathology Semester: 4th

Name: Dr. Fazal-Ur-Rehman Bangash

Fathers Name: Abdur Rehman Bangash

Contact No: 03339119474

Email: xray2002\_3@yahoo.com

Name & Designation of Supervisor: Prof. Dr. Arshad Parvez, Prof. of Chemical Pathology Khyber Girls Medical College Hayatabad Peshawar.

Type of Participants: Humans  Animals \_\_\_\_\_ others (specify): \_\_\_\_\_

Status of Submission: 1): Fresh \_\_\_\_\_ 2): Revised:  Duration of Data collection: Five months

Title of the project: "Clinical improvement in psoriasis with treatment of associated dyslipidemia".

Please tick the following checklist before submission:

Work plan/Gantt Chart attached:	Yes / No
Proposal attached as per format provided by KMU-AS&RB:	Yes / No
Approved by Graduate Committee:	Yes / No
Ethical Approval obtained:	Yes No In process
KMU dues submitted and up to date:	Yes / No
Covering Letter Attached:	Yes / No
2 copies of proposals and all supplementary documents attached:	Yes / No
Plagiarism Certificate attached	Yes / No
Course Completion certificate attached	Yes / No

Candidate Signature: *Fazal-Ur-Rehman Bangash*

Supervisor Signature and Stamp: \_\_\_\_\_

Head Deptt. of Pathology  
KGMC Peshawar



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Supervisor Signature: \_\_\_\_\_

*[Handwritten Signature]*

Member-1

Name & Signature: \_\_\_\_\_

*Prof. Dr. Amir Muhammad*

Member-2

Name & Signature: \_\_\_\_\_

*PROF. DR. NIAZ MUHAMMAD*

Member-3

Name & Signature: \_\_\_\_\_

*Prof. Dr. Khalid Javed*

Member-4

Name & Signature: \_\_\_\_\_

*Prof. Dr. Abdul Hamid Khan*

Prof. Dr. Amin-Ul-Haq  
Associate Dean, PGMED

Signature: \_\_\_\_\_

*Amin-ul-Haq*



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## Smokeless Tobacco control in Khyber Pakhtunkhwa, Pakistan (STOP): mixed method research

ORIGINALITY REPORT

**13%**

SIMILARITY INDEX

**11%**

INTERNET SOURCES

**12%**

PUBLICATIONS

**%**

STUDENT PAPERS

PRIMARY SOURCES

- 1** Zakiullah. "Assessment of potential toxicity of a smokeless tobacco product (naswar) available on the Pakistani market", Tobacco Control, 06/03/2011  
Publication **2%**
- 2** www.austlii.edu.au  
Internet Source **2%**
- 3** apps.who.int  
Internet Source **2%**
- 4** Paul Cairney, Donley T. Studlar, Hadii M. Mamudu. "Global Tobacco Control", Springer Nature, 2012  
Publication **2%**
- 5** www.janspitcsdelft.nl  
Internet Source **1%**
- 6** Siddiqi, K., K. Scammell, R. Huque, A. Khan, S. Baral, S. Ali, and I. Watt. "Smokeless tobacco supply chain in South Asia: A comparative analysis using the WHO Framework **1%**



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No: \_\_\_\_\_

Date: \_\_\_\_\_

**RESEARCH PROPOSAL TEMPLATE**

**CLINICAL IMPROVEMENT IN PSORIASIS WITH TREATMENT OF ASSOCIATED  
DYSLIPIDEMIA.**

**Name of Candidate: Fazal-Ur-Rehman Bangash**

**Name of Supervisor: Prof. Dr. Arshad Pervez**

**Duration of Project: Eight months after approval by AS & RB KMU**

**Institute: Khyber Girls Medical College Hayatabad Peshawar**

**Budget Required: Rs. 134 000/--**

**Name & Signature of Scholar: Fazal-Ur-Rehman Bangash \_\_\_\_\_**

**Name & Signature of the Supervisor: Prof. Dr. Arshad Pervez \_\_\_\_\_**

**Name & Signature of Associate Dean: Prof. Dr. Amin-ul-Haq \_\_\_\_\_**



**1. TITLE:**

**CLINICAL IMPROVEMENT IN PSORIASIS WITH TREATMENT OF ASSOCIATED DYSLIPIDEMIA.**

**2. INTRODUCTION:**

Psoriasis is a debilitating proliferative and chronic inflammatory skin disease while dyslipidemia is the presence of one or more deranged value(s) of lipid(s) in the blood. Global prevalence of psoriasis patients ranges from 2% to 4%.<sup>1</sup> There is a significant variation of global incidence of psoriasis.<sup>2</sup> Data is scarce regarding prevalence and incidence of psoriasis in Pakistan.<sup>3</sup> It is assumed to be a common problem on the basis of daily outdoor patient department (OPD) attendance.

It is evident that psoriasis has an association with cardiovascular risk factors like diabetes mellitus (DM), hypertension, obesity, hyperlipidemia and smoking.<sup>4</sup> Research work on metabolism of lipids especially in the field of psoriasis started in the 1<sup>st</sup> decade of 20<sup>th</sup> century by quantitatively analyzing cholesterol in the serum of psoriasis patients.<sup>5</sup>

Among previously conducted studies in psoriasis patients, statistical significant raised levels of lipid profile (low-density lipoprotein, total cholesterol, and / or triglycerides) were seen.<sup>6, 7, 8</sup>

Very few studies have been conducted in Pakistan to show association between dyslipidemia and psoriasis.<sup>3,7</sup> Further more in Pakistan very little work has been done in the field of of dyslipidemic psoriasis patients on statin therapy as in the last few years their anti-inflammatory and immunomodulatory effects have also been described which may benefit psoriasis patients.<sup>9</sup>

Till date a single study has been conducted in Pakistan where in psoriasis patients only clinical effect of statin has been studied.<sup>9</sup>

The rationale of my research is to further study the effect of statin on levels of dyslipidemia and clinical improvement in severity of psoriasis as no such study in the whole Pakistan has been conducted so far.



### 3. OBJECTIVES:

- To determine efficacy of statin therapy in terms of improvement of serum lipid profile (LDL, Total cholesterol, VLDL, TG , HDL ) levels and PASI score in patients having psoriasis.

### 4. OPERATIONAL DEFINITIONS:

**Psoriasis:** It is a proliferative and chronic inflammatory skin disease with clinical manifestation of well-demarcated, dull red or salmon pink scaly papules and plaques located on extensor surfaces of limbs (especially knees, elbows and shins), lower back / buttocks and scalp but it may affect body's any part.

**Lipid profile:** Following are the representative components of normal lipid profile: <sup>10</sup>

- Serum total cholesterol < 200 mg/dL;
- Serum low density lipoprotein in normal individuals < 100 mg/dL while in diabetics < 130 mg/dL ;
- Serum triglyceride for males < 160 mg/dL and for females < 135mg/dL;
- Serum very low density lipoprotein < 40 mg/dL;
- Serum high density lipoprotein for males > 40 mg/dL and for females > 50 mg/dL;

Dyslipidemia is the presence of abnormal amount of one or more of the above component(s) in the blood. Patients will also be having dyslipidemia if they are on medication for the deranged value(s) of any of the above.

**Body Mass Index (BMI):** It is body fat measurement based on weight to height relation (for adults) i.e.  $BMI = \text{Kg}/\text{M}^2$  .

- Underweight: ( BMI < 18.5) ;
- Normal Weight: (BMI 18.5 to 24.9);
- Overweight: (BMI 25 to 29.9);
- Obese: BMI 30 and above.

**Statins:** This is a group of lipid lowering agents but in the last few years their anti-inflammatory and immunomodulatory effects have also been described which may benefit psoriasis patients. <sup>9</sup>



**PASI Score:** The measurement of psoriasis severity is done with the help of Psoriasis Area and Severity Index. This index takes into account the lesion coverage area (calculated as the percentage of the affected body surface area) along with the plaque appearance (redness, thickness and scales formation).

Interpretation of PASI score :

- Equal to or less than 10 means mild psoriasis
- Greater than 10 means moderate to severe psoriasis.

## 5. HYPOTHESIS :

Statin therapy decreases dyslipidemia and as a result clinically improves severity of psoriasis.

## 6. MATERIALS AND METHODS:

**6a. Study Design:** My study will be randomized control trial.

**6b. Study Settings:** My research will be conducted at dermatology department of Hayatabad Medical Complex Peshawar. Patients having psoriasis will be enrolled from dermatology unit Hayatabad Medical Complex Peshawar. Laboratory investigations for serum lipid profile will be done in pathology department laboratory of Khyber Girls Medical College Hayatabad Peshawar.

**6c. Study Duration:** Eight months from the approval of synopsis by Advanced Studies and Research Board (ASRB) of Khyber Medical University (KMU).

## 6d. Sample Size:

Sample size is calculated through “OpenEpi” sample size calculator.

Two-sided significance level(1-alpha): 95  
Power(1-beta, % chance of detecting): 80  
Ratio of sample size, Unexposed/Exposed: 1





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Percent of Unexposed with Outcome:	20
Percent of Exposed with Outcome:	60
Risk/Prevalence Ratio:	3
Risk/Prevalence difference:	40

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Sample Size – Intervention group:	24
Sample Size – Control group:	24

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Total sample size:	48
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So we have Sample Size  $n=48$ .

But I will take sample size of 60 due to loss to follow-up.

**6e.Sampling Technique:** It will be non probability consecutive sampling technique by lottery method.



## 7. SAMPLE SELECTION:

### 7a. Inclusion Criteria:

- Participants of both genders having dyslipidemia;
- Age of participants in my study will be 18 years and above;
- Patients having psoriasis history more than 1 year.

### 7b. Exclusion Criteria:

- Subjects who are smokers;
- Obese subjects having BMI 30 and above ;
- Female subjects who are pregnant , lactating mothers or on any kind of hormonal contraceptives;
- Subjects self reportedly diagnosed as patients of Type 2 Diabetes Mellitus , Hypertension , Chronic liver disease, Chronic Renal Failure;
- Subjects who already take lipid lowering agents or whose lipid profile is normal.

## 8. DATA COLLECTION PROCEDURE:

A detailed medical history and physical examination will be conducted on all participated psoriasis patients (diagnosed by assistant professor and above level consultants of dermatology unit Hayatabad Medical Complex Peshawar) after taking their written informed consent. Height will be measured in metres, weight in kilograms and blood pressure will be recorded as well. 3 ml blood sample will be taken from 12 hourly or more fasting individuals, by venipuncture from cubital vein and kept in ice packs until transferred to pathology department laboratory of Khyber Girls Medical College Hayatabad where it will be centrifuged. Serum lipid profile will be estimated by enzymatic colorimetric method on spectrophotometer (Merck Microlab 300 made in Japan) and DiaSys kits (made in Germany) in the same laboratory according to protocol and remaining sera will be preserved at minus 75 C<sup>0</sup> in wisecryo (wisdom laboratory instruments made in Japan). Then PASI score of all eligible participants of study will be recorded. All the participants will randomly be divided into intervention and control groups by lottery method through choosing an envelop of their choice. Participants of intervention group will be provided statin 10 mg daily dose for 12 weeks. Both groups will continue taking conventional psoriasis treatment. After 12 weeks, on follow-up visit of both groups, PASI score and lipid profile will again be reassessed.



**8a. Laboratory Procedure:** First of all microlab is calibrated for error for which with the help of micropipette 1000 microlitres of purchased reagent and 10 microlitres standard (has already known value) is mixed and incubated in waterbath for 5 minutes. Then this mixture is analysed in microlab and the reading is taken to know whether there is an error or the analyser is properly working. After calibration we start working with our sera samples. Take 1000 microlitres of reagent and put 10 microlitres of serum sample in it. Incubate this mixture in 37 C<sup>0</sup> water bath for 5 minute after which mixture is analysed automatically in microlab for taking result.

**8b. Test Principle:** Serum lipid profile analysis is a colorimetric procedure which is measured by spectrophotometer. The working principle of spectrophotometer is measurement of amount of light which a sample absorbs. Light is passed through sample that is detected by a detector which measures the intensity of passing light through the sample. When this passed light hits detector, it is shown on digital meter in the form of digits.

**8c. Methodology:** Enzymatic colorimetric spectrophotometry.

## 9. DATA ANALYSIS PROCEDURE:

The obtained results of the research will be put in tables and will be coded for review. Paired sample t-test will be used by Statistical Package for Social Science (SPSS) version 21 and the yield will be expressed in the form of p-value. p-values = or < 0.05 will be statistically considered significant.



## 10. BIBLIOGRAPHY:

1. Parisi R, Symmons DPM, Griffiths CEM, Ashcroft DM. Global Epidemiology of Psoriasis: A Systematic Review of Incidence and Prevalence. *J Invest Dermatol.* 2013 Feb;133(2):377–85.
2. Michalek IM, Loring B, John SM. A systematic review of worldwide epidemiology of psoriasis. *J Eur Acad Dermatology Venereol.* 2017;31(2):205–12.
3. Ejaz A, Suhail M, Iftikhar A. Psoriasis in pakistani population: Associations, comorbidities and hematological profile. *J Pakistan Assoc Dermatologists.* 2013;23(1):42–6.
4. Egeberg A. Psoriasis and comorbidities. *Epidemiological studies. Dan Med J.* 2016;63(2):1–11.
5. Chibowska M. Role of serum lipids in psoriasis. *Przegl Dermatol.* 1970 ;57(2):255–60.
6. Ghafoor R, Rashid A, Anwar MI. Dyslipidemia and Psoriasis: A Case Control Study. *J Coll Physicians Surg Pak.* 2015 May ; 25(5):324–7.
7. Arora T, Krishna A, Rathore B, Srivastava D. Association of dyslipidemia with psoriasis: A case-control study. *J Obes Metab Res.* 2016;3(1):37.
8. Nakhwa YC, Rashmi R, Basavaraj KH. Dyslipidemia in Psoriasis: A Case Controlled Study. *Int Sch Res Not.* 2014 Oct 8;2014:1–5.
9. Aslam S, Khurshid K, Asad F, Rani Z, Pal SS. Efficacy and safety of simvastatin in chronic plaque psoriasis. *J Pakistan Assoc Dermatologists.* 2013;23(3):310–4.
10. Nordestgaard BG, Langsted A, Mora S, Kolovou G, Baum H, Bruckert E, et al. Fasting is not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cut-points—a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine. *Eur Heart J.* 2016 Jul 1;37(25):1944–58.



**BUDGET ESTIMATION REPORT:**

<b>ACTIVITY/ TASK.</b>	<b>PRICE ESTIMATION.</b>
Proposal development.	Rs. 2000/--
Proposal approval & acquisition of NOCS from collaborative centers.	Rs. 2000/--
Proformas and Medicine (Statin 10 mg).	Rs. 30000/--
Samples procedures / Processing.	Rs. 90000/--
Data analysis and paper writing.	Rs. 5000/--
Thesis writing.	Rs. 5000/--
Total.	Rs. 134000/--





**PROFORMA :**

**CLINICAL IMPROVEMENT IN PSORIASIS WITH TREATMENT OF ASSOCIATED  
DYSLIPIDEMIA.**

**Intervention group / Control group.**

Serial No: -----

Date: -----

Name: ----- Age: ----- Gender: ---

Address: ----- Mobile # -----

Blood Pressure: ---/---mmHg. Height: -----m. Weight: -----kg ; BMI=kg/m<sup>2</sup> = -----

Present history of illness: -----

Past history of illness: -----

Family history of illness: -----

Any drug taking history: -----

Duration of Psoriasis -----Area involved-----

PASI Score 1<sup>st</sup> visit-----

PASI Score F.Up visit after 12 weeks -----

**LABORATORY INVESTIGATIONS:**

NO.	INVESTIGATION	NORMAL VALUE	SUBJECT'S VALUE	
			1 <sup>st</sup> Visit	F.Up Visit
1	Total cholesterol	<200 mg/dL (<5.18mmol/L)		
2	Triglycerides	Male<160mg/dL (<1.8mmol/L) Female<135mg/dL (<1.52mmol/L)		
3	HDL cholesterol	Male>40mg/dl (>1.0mmol/L) Female>50mg/dl (>1.3mmol/L)		
4	LDL cholesterol	<100mg/dl (<2.59mmol/L)		
5	VLDL cholesterol	<40mg/dl (<1.0mmol/L)		



## **PARTICIPANT INFORMATION SHEET:**

This sheet is for participants whom we are inviting to participate in research on improvement of psoriasis with statin therapy. The title of our research project is "clinical improvement in psoriasis with treatment of associated dyslipidemia".

### **Introduction:**

I am Dr.Fazal-Ur-Rehman Bangash, working in Pathology department of Khyber Girls Medical College Hayatabad. I am doing research on psoriasis and dyslipidemia. I am going to give you information and invite you to be part of this research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain.

### **Purpose of the research:**

Psoriasis is one of the common diseases in our country. The drugs that are currently used to help people with psoriasis are not as good as we would like them to be. In fact, conventional psoriasis treatment is helpful up to a certain limit and time period. There is a drug which may work better along with conventional treatment. The reason we are doing this research is to find out if the new drug statin is better than the only conventional treatment which is currently being used.

### **Type of Research Intervention:**

This research will involve a single tablet of statin 10 mg to be taken by mouth at night time before going to bed along with traditional treatment for 12 weeks for the intervention group and only conventional treatment for the control group for the same time period.

### **Participant selection:**

We are inviting all adults of age 18 years and above having psoriasis, fulfilling inclusion and exclusion criteria, who attend skin unit of Hayatabad Medical Complex Peshawar to participate in the research on improvement of psoriasis with statin therapy.

### **Voluntary Participation:**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not, all the services you receive at this hospital will be continued and nothing will be changed. You may change your mind later and stop participating even if you agreed earlier.

### **Information on the Statin:**

The drug we are testing in this research is called statin. It has been tested before abroad with people who had psoriasis. Now we want to test the drug on people of Pakistan especially Khyber Pakhtunkhwa. There is no risk associated with that and no known problems.

Some participants in the research will not be given the drug which we are testing. Instead, they will continue their traditional treatment.

### **Procedures and Protocol:**

#### **A. Unfamiliar Procedures:**

Because we do not know if the drug statin is better with the conventional treatment of psoriasis or not, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, i.e. by lottery method.

Participants in one group will be given the test drug along with continuation of conventional treatment while participants in the other group will continue only conventional treatment for psoriasis. We will then compare which of the two has the best results.

I will be sending you daily SMS alerts at the time of taking drug during the study. If there is anything you are concerned about or that is bothering you about the research please talk to me.

I will take 3 ml venous blood from your arm using a syringe and needle today and on follow up visit after 12 weeks. At the end of the research, in eight months, any left over blood sample will be destroyed.



**B. Description of the Process:**

During the research you make two visits to the skin unit of Hayatabad Medical Complex Peshawar.

- In the first visit severity of psoriasis will be scored and 3 ml of blood will be taken from your arm with a 5 ml syringe. This blood will be tested for the levels of different fats in your body. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.
- At the next visit, which will be twelve weeks later, you will come back to the skin unit of Hayatabad Medical Complex Peshawar for a review. This review will include fats levels estimation in your blood and reassessment of severity of psoriasis.

**Duration:**

The research takes place over twelve weeks. We would like to meet with you after twelve weeks for follow up check-up. At the end of eight months, the research will be finished.

**Benefits:**

There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

**Confidentiality:**

We will not share the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?



**CERTIFICATE OF PARTICIPANT CONSENT:**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

If illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness \_\_\_\_\_

AND

Thumb impression of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. History taking ,Physical and clinical examination of the patient.
2. 3 ml venous blood taking from the arm of participant for lipid profile.
3. PASI scoring.
4. Provision of tab.statin 10 mg ( 90 tablets for 12 weeks duration) to eligible participants of intervention group.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has given consent freely and voluntarily.

Name of Researcher/person taking the consent \_\_\_\_\_

Signature of Researcher /person taking the consent \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year



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**شراک تدارک کا معلوماتی پرچم:**

یہ شیٹ ان شرکاء کے لئے ہے جو ہم statin علاج کے ساتھ چنبل کے بہتری پر تحقیق میں حصہ لینے کے لئے دعوت دے رہے ہیں۔  
ہمارے تحقیقی منصوبے کا عنوان ہے "متعلقہ چربی میں خرابی کے علاج کے ساتھ چنبل میں طبی بہتری"۔

**تعارف:**

میں ڈاکٹر فضل الرحمن بنگش ہوں اور لڑکیوں کے لیے خیبر میڈیکل کالج حیات آباد کے پاتھولوجی ڈپارٹمنٹ میں کام کر رہا ہوں۔ میں چنبل اور چربی میں خرابی پر تحقیق کر رہا ہوں۔ میں آپ کو معلومات دینے جا رہا ہوں اور آپ کو اس تحقیق کا حصہ بنانا چاہتا ہوں۔  
شاید کچھ الفاظ جو آپ سمجھتے نہیں ہیں۔ براہ کرم مجھ سے پوچھیں کہ جب ہم معلومات کے ذریعے جاتے ہیں تو مجھے روکنے کے لئے وقت لگے گا۔

**تحقیق کا مقصد:**

ہمارے ملک میں عام بیماریوں میں سے ایک چنبل ہے۔ جو ادویات اس وقت چنبل کے ساتھ لوگوں کی مدد کرنے کے لئے استعمال ہوتے ہیں وہ اچھے نہیں ہیں۔ حقیقت میں، روایتی چنبل علاج بعض حدوں اور وقت کی مدت تک مددگار ثابت ہوتا ہے۔ statin جو روایتی علاج کے ساتھ بہتر کام کر سکتے ہیں۔ ہم یہ تحقیق کر رہے ہیں اس وجہ سے یہ معلوم کرنا ہے کہ نئی statin صرف روایتی علاج سے بہتر ہے، جو اس وقت استعمال کیا جا رہا ہے۔

**ریسرچ مداخلت کی قسم:**

اس تحقیق میں مداخلت کے گروپ کے لئے روایتی علاج اور بطور منہ 10 ملی گرام کی متعلقہ statin کی ایک گولی ایک ہی وقت کی مدت کے لئے صرف روایتی علاج کے لئے روایتی علاج شامل ہے۔

**شرکاء کا انتخاب:**

ہم 18 سال اور اس سے زیادہ عمر کے تمام چنبل کے بالغوں کو شامل کرنے اور شامل کرنے کے معیار کو پورا کرنے کے لئے دعوت دے رہے ہیں، جنہوں نے حیات آباد میڈیکل کمپلیکس پشاور کے جلد یونٹ میں چنبل کے بہتری پر تحقیق کے لئے حصہ لیا۔  
رضاکارانہ شرکت:

اس تحقیق میں آپ کی شرکت مکمل طور پر رضاکارانہ ہے۔ یہ آپ کی پسند ہے حصہ لینے کے، اس ہسپتال میں آپ ہر قسم کے علاج کا حصول جاری رکھیں گے اور کچھ بھی نہیں بدل جائے گا۔ آپ بعد میں حصہ لینے کو روک سکتے ہیں۔

**statin پر معلومات:**

ہم اس تحقیق میں statin کی جانچ کر رہے ہیں جنکو چنبل تھا۔ ان سے پہلے یہ تجربہ کیا گیا ہے۔ ہم اب پاکستان خاص طور پر خیبر پختونخواہ کے عوام پر منشیات کی جانچ کرنا چاہتے ہیں۔ اس statin سے متعلق کوئی خطرہ نہیں ہے اور کوئی مسئلہ نہیں۔  
تحقیق میں کچھ شرکاء کو statin نہیں دی جائے گی جسے ہم جانچ کر رہے ہیں۔ اس کے بجائے، وہ اپنے روایتی علاج جاری رکھیں گے۔

**طریقہ کار اور پروٹوکول:**

**1. نا واقف طریقہ کار:**

کیونکہ ہم نہیں جانتے ہیں کہ statin کی روایتی علاج کے ساتھ چنبل کی حالت بہتر ہے یا نہیں، دونوں کی موازنہ کرنے کی ضرورت ہے۔ ایسا کرنے کے لئے، ہم اس تحقیق میں حصہ لینے والے افراد کو دو گروپوں میں ڈال دیں گے۔ گروپوں کو لائٹری طریقہ کے ذریعہ منتخب کیا جاتا ہے۔

ایک گروپ میں شرکاء کو روایتی علاج کے تسلسل کے ساتھ statin بھی دی جائے گی جبکہ دوسرے گروپ میں شرکاء صرف چنبل کے لئے روایتی علاج جاری رکھیں گے۔ ہم اس کا موازنہ کریں گے کہ دونوں میں سے کون سے بہترین نتائج ہیں۔

میں تجزیہ کے دوران statin لینے کے وقت میں آپ کو یومیہ ایس ایس الٹ بھیجوں گا۔ اگر آپ کے بارے میں فکر مند چیز ہے یا آپ کو تحقیق کے بارے میں پریشان کر رہا ہے تو براہ مہربانی مجھ سے بات کریں۔

میں آج آپ کے بازو سے 3 ملی لیٹر وینس خون لے کر سرنج اور انجکشن کا استعمال کرتے ہوئے اور 12 ہفتوں کے بعد کی پیروی کرنے کے بعد لے جاؤں گا۔ تحقیق کے اختتام پر، آٹھ ماہ میں، خون کا نمونہ تباہ ہو جائے گا۔

**2. عمل کی تفصیل:**

تحقیق کے دوران آپ حیات آباد میڈیکل کمپلیکس پشاور کے جلد یونٹ میں دو دورہ کرتے ہیں۔

• پہلی دورہ میں سکور بنائے جائیں گے اور 5 ملی لیٹر سرنج کے ساتھ خون کے 3 ملی لیٹر آپ کے بازو سے لے جائیں گے۔ یہ خون آپ کے جسم میں مختلف چربی کی سطح کے لئے ٹیسٹ کیا جائے گا۔ ہم آپ کو آپ کے عام صحت کے بارے میں کچھ سوالات بھی پوچھیں گے اور اس بات کی پیمائش کریں گے کہ آپ کتنے لمبے ہیں اور آپ کتنے وزنی ہیں۔

• اگلے دورے پر، جو بارہ ہفتوں بعد ہو گا، آپ حیات آباد میڈیکل کمپلیکس پشاور کے جلد یونٹ میں واپس آئیں گے۔ اس جائزے میں آپ کا خون اور چنبل کی شدت کی دوبارہ بازیابی میں چربی کی سطح کا اندازہ شامل ہوگا۔

**دورانیہ:**

یہ تحقیق بارہ ہفتوں کی ہے۔ ہم بیگ اپ چیک کرنے کے لئے بارہ ہفتوں کے بعد آپ سے ملنا چاہتے ہیں۔ آٹھ ماہ کے اختتام پر، تحقیق ختم ہو جائے گی





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فوائد:

آپ کے لئے کوئی فائدہ نہیں ہو سکتا لیکن آپ کی شرکت تحقیق کے سوال کے جواب کو تلاش کرنے میں مدد مل سکتی ہے۔ تحقیق کے اس مرحلے میں معاشرے کو کوئی فائدہ نہیں ہو سکتا ہے، لیکن مستقبل کی نسلیں فائدہ اٹھانے کا امکان ہے۔

رازداری:

ہم تحقیق میں حصہ لینے والوں کی شناخت نہیں کریں گے۔

اس تحقیقاتی منصوبے سے متعلق معلومات کو خفیہ رکھا جائے گا۔ آپ کے بارے میں معلومات جو تحقیق کے دوران جمع کیے جائیں گے انہیں دور رکھا جاسکتا ہے اور نہ ہی کوئی محققین اسے دیکھ سکیں گے۔ آپ کے بارے میں کوئی معلومات آپ کے نام کے بجائے اس پر ایک نمبر پڑے گا۔ صرف محققین یہ جان لیں گے کہ آپ کا نمبر کیا ہے اور ہم اس معلومات کو تالا اور کلید کے ساتھ بند کر دیں گے۔ اگر آپ چاہیں تو تحقیق کے مطالعہ کے کسی بھی حصے کے بارے میں مزید سوالات مجھ سے پوچھ سکتے ہیں۔ کیا آپ کے پاس کوئی سوال ہے؟



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**شراک تدار کی تصدیقہ**

میں نے مشترکہ معلومات پڑھی ہیں، یا یہ مجھے پڑھائے گئے ہیں۔ مجھے اس کے بارے میں سوالات پوچھنے کا موقع ملا ہے اور جس سے میں نے پوچھا ہے کہ میری اطمینان کا جواب دیا گیا ہے۔ میں رضاکارانہ طور پر اس تحقیق میں حصہ لینے والے کے طور پر حصہ لینے کی رضامندی کرتا ہوں۔

حصہ لینے والے کا نام \_\_\_\_\_  
شراکت دار کا دستخط \_\_\_\_\_  
تاریخ \_\_\_\_\_  
دن / مہینے / سال \_\_\_\_\_

اگر غیر معمولی:  
میں ممکنہ شراکت دار رضاکارانہ رضامندانہ رضامندی کا جائزہ لے رہا ہوں، اور اس سے سوالات کرنے کا موقع ملا ہے۔ میں اس بات کی تصدیق کرتا ہوں کہ فرد نے آزادانہ طور پر رضامندیاں دی ہیں۔

گواہ کا نام \_\_\_\_\_ اور شرکت کنندہ کے انگوٹھے \_\_\_\_\_  
گواہ کا دستخط \_\_\_\_\_  
تاریخ \_\_\_\_\_  
دن / مہینے / سال \_\_\_\_\_

رضاکارانہ شخص / رضامند ہونے سے متعلق بیان:

میں نے ممکنہ شراکت دار کو معلوماتی شیٹ کو درست طریقے سے پڑھا ہے، اور اپنی صلاحیت کو بہتر بنایا ہے کہ اس بات کو یقینی بنائے کہ شراکت کو یہ سمجھا جاتا ہے کہ مندرجہ ذیل کام کئے جائیں گے:

1. تاریخ لینے، مریض کی جسمانی اور کلینک کی امتحان۔
2. لیڈ پروفائل کے لئے حصہ لینے والے کے بازو سے 3 ملی لیٹر وینس خون لینا۔
3. PASI اسکور۔
4. مداخلت گروپ کے اہل شرکاء کے لئے ٹیب۔سٹنٹن 10 ملیگرام (12 ہفتوں کے لئے 90 گولیاں) کی فراہمی۔

میں اس بات کی تصدیق کرتا ہوں کہ شرکاء کو اس مطالعہ کے بارے میں سوالات پوچھنے کا موقع دیا گیا، اور شراکت دار سے پوچھے گئے تمام سوالوں کو صحیح جواب دیا گیا ہے۔ میں اس بات کی تصدیق کرتا ہوں کہ فرد نے آزادانہ طور پر رضاکارانہ طور پر شرکت کے لئے رضامند ہے۔

مشیر لینے والے شخص کا نام \_\_\_\_\_  
رضاکارانہ لینے والے شخص / رضاکارانہ دستخط \_\_\_\_\_  
تاریخ \_\_\_\_\_  
دن / مہینے / سال \_\_\_\_\_



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A representative area of psoriasis is selected for each body region. The intensity of redness, thickness and scaling of the psoriasis is assessed as none (0), mild (1), moderate (2), severe (3) or very severe (4).

	Head & Neck	Upper Limbs	Trunk	Lower Limbs
<b>Erythema or Redness (0-4)</b>				
<b>Induration or Thickness (0-4)</b>				
<b>Scales (0-4)</b>				
<b>SUM (E+I+S)</b>				
Body surface Area (1-6)				
<b>(Sum) x (Body surface area)</b>				
Area multiplier	0.1	0.2	0.3	0.4
<b>(Sum) x (Area multiplier)</b>	( ) X (0.1) =	( ) X (0.2) =	( ) X (0.3) =	( ) X (0.4) =

**TOTAL PASI SCORE =**

### GANTT CHART

<b>Clinical improvement in psoriasis with treatment of associated dyslipidemia.</b>											
ACTIVITY/ TASK	2017	2018									
	Dec.	Jan.	Feb.	Mar.	Apr.	May	June	July.	Aug.	Sept.	
Proposal development.	⇒										
Proposal approval & acquisition of NOCS from collaborative centers.		⇒									
Sampling.		⇒									
Procedures.						⇒					
Data analysis and paper writing.								⇒			
Thesis writing & submission.									⇒		