

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Dec 2019

### Evaluation of the effect of *Arnebia euchroma* - *Calendula officinalis* - *Zataria multiflora* and sesame oil lipogel formulation on post- tattoos complication prevention of in comparison to gentamicin:a randomized clinical trial

#### Protocol summary

##### Study aim

Effect of lipogel containing *Arnebia euchroma* - *Calendula officinalis* -*Zataria multiflora* and sesame oil on skin restoration complications after tattoo

##### Design

The total sample size is 45, of which half are in the gentamicin group and half of the lipogel group. A diagnosis of a patient is done with a study by a dermatologist. Triple blind study. People should not have skin diseases such as vitiligo, burns and so on. The use of any skin-related product during treatment is under the supervision of a dermatologist

##### Settings and conduct

A study in the skin and hair clinic under the supervision of Dermatologist Dr. Rahmatpour. Coded products are randomly assigned to patients

##### Participants/Inclusion and exclusion criteria

Inclusion ceriteria:Admission age between the ages of 18 and 65, a person with full skin health, menopause or those undergoing sterilization surgery is advised by the doctor; tattoo size is less than 30 cm. Exclusion ceriteria:Age over 65 or under 18; pregnant woman; people with skin diseases such as vitiligo, yellow, burn etc; tattoo size greater than 30 cm

##### Intervention groups

The study consists of two groups of control and drug recipients. The lipogel group received the extract containing the drug and the control group received gentamicin. The lipogel and the gentamicin are twice daily rubbed over to the entire eyelid and not repaired for 1 hour.

##### Main outcome variables

Study of complications after tattoo by lipogel compared to gentamicin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130911014630N5**

Registration date: **2019-04-21, 1398/02/01**

Registration timing: **retrospective**

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

##### Registration date

2019-04-21, 1398/02/01

##### Registrant information

###### Name

Mohammad Azadbakht

###### Name of organization / entity

Mazandaran University of Medical Scinecece

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1214 4052

###### Email address

mazadbakht@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-03, 1397/12/12

##### Expected recruitment end date

2019-03-11, 1397/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of *Arnebia euchroma* - *Calendula officinalis* -*Zataria multiflora* and sesame oil lipogel formulation on post- tattoos complication prevention of in comparison to gentamicin:a randomized clinical trial

##### Public title

Evaluation of the effect of *Arnebia euchroma* - *Calendula officinalis* -*Zataria multiflora* and sesame oil lipogel

formulation on post- tattoos complication prevention of in comparison to gentamicin:a randomized clinical trial

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of admission is between 18 and 65 years,The tattoos should not be larger than 12 inches;The tattoos must be dressed or bandaged and not exposed to sunlight, otherwise you should use an anti-sun lamp with a spf above 50;Individuals should be inclined to take digital photographs of the area they are able to reach for educational and scientific purposes;Not pregnant people;Menopause or who have undergone sterilization surgery can attend a doctor's review.

### Exclusion criteria:

Participation in a clinical trial of a drug or another device in the target area within 3days prior to enrollment or during the study. • History of allergic reaction to pigments following tattooing. • History of allergy to local anesthetics. • History of allergy to topical antibiotics. • History of malignant tumors in the target area. • Skin abnormalities in the target area, e.g., cuts, scrapes, wounds, scars, large moles. • Pregnant and/or breastfeeding. • Having an infection, dermatitis or a rash in the treatment area. • Significant concurrent illness, such as diabetes mellitus or cardiovascular disease, e.g., uncontrolled hypertension. • Suffering from coagulation disorders or taking prescription anticoagulation medications. • History of keloid scarring, hypertrophic scarring or of abnormal wound healing. • History of immunosuppression/immune deficiency disorders or currently using immunosuppressive medications. • History of vitiligo, eczema, or psoriasis. • History of connective tissue disease, such as systemic lupus erythematosus or scleroderma. • History of seizure disorders due to light. • Any use of medication that is known to increase sensitivity to light according to Investigator's discretion. • History of disease stimulated by heat, such as recurrent herpes simplex and/or herpes zoster (shingles) in the treatment area, unless treatment is conducted following a prophylactic regimen • History of radiation to the treatment area or undergoing systemic chemotherapy for the treatment of cancer. • History of pigmentary disorders, particularly tendency for hyper- or hypo-pigmentation. • Systemic use of corticosteroid or isotretinoin within 3days of study participation. • Current smoker or history of smoking within 3days of study participation. • As per the Investigator's discretion, any physical or mental condition which might make it unsafe for the subject to participate in this study.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization, individual, using random numbers table

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

In this study, the dermatologist and the patients and the investigator have no information about gentamicin or lipogel, and the product has predetermined codes and is given randomly to patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

farah abad street

##### City

sari

##### Province

Mazandaran

##### Postal code

4847191971

#### Approval date

2019-03-12, 1397/12/21

#### Ethics committee reference number

IR.MAZUMS.RIB.REC.1398.001

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

Prevention of complications after tattoo

#### Timepoint

At least twice a day for 3 days

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The lipogel containing extract is used twice daily to cover the entire eyebrow. For this purpose, 23 patients are selected according to the conditions of entry requirements. These people receive lipogel medications containing 5% of the extract Arnebia euchroma, 2% of the extract Calendula officinalis, 3% of extract Zataria multiflora, 20% of sesame oil for three days under supervision of a dermatologist and in collaboration with the project implementer. To make 100 grams of lipogel, 10 grams of polyethylene and 90 grams of paraffin are used. Extract of Arnebia euchroma, Calendula officinalis-Zataria multiflora and sesame oil, is expected to have an effect on inflammation, scar tissue and scaling, which can improve the damaged skin. Should not be showered until 12 hours after use. This lipogel was made at the laboratory of the Mazandaran-Sari Pharmaceutical Faculty.

#### Category

Prevention

### 2

#### Description

Control group: Includes gentamicin from the pharmacy, that is spilled in lipogel's tubes and can not be identified, and the codes inserted on the product is the only way to identify. Twice daily, the eyebrows should be completely covered with the lipogel and Do not shower until 12 hours after use.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

کلینیک پوست و مو دکتر رحمت پور

##### Full name of responsible person

dr rahmatpour

##### Street address

farhang street

##### City

sari

##### Province

Mazandaran

##### Postal code

4847191971

##### Phone

+98 11 3354 2472

#### Email

nazanin.yousefi.72@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sari University of Medical Sciences

##### Full name of responsible person

dr mohammad azadbakht

##### Street address

farah abad street

##### City

sari

##### Province

Mazandaran

##### Postal code

4847191971

##### Phone

+98 11 3354 2472

##### Email

azadbakhtm@hotmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sari University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sari University of Medical Sciences

##### Full name of responsible person

nazanin yousefi

##### Position

Pharmacy student of Sari University of medical sciences

##### Latest degree

A Level or less

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

farah abad street

##### City

sari

##### Province

Mazandaran  
**Postal code**  
 4847191971  
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**Email**  
 nazanin.yousefi.72@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
 Sari University of Medical Sciences  
**Full name of responsible person**  
 dr mohammad azadbakht  
**Position**  
 Professor  
**Latest degree**  
 Ph.D.  
**Other areas of specialty/work**  
 Medical Pharmacy  
**Street address**  
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**City**  
 sari  
**Province**  
 Mazandaran  
**Postal code**  
 4847191971  
**Phone**  
 +98 11 3354 2472  
**Email**  
 azadbakhtm@hotmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
 Sari University of Medical Sciences  
**Full name of responsible person**  
 nazanin yousefi  
**Position**  
 Pharmacy student of Sari University of medical sciences  
**Latest degree**  
 A Level or less  
**Other areas of specialty/work**

Medical Pharmacy  
**Street address**  
 farah abad street  
**City**  
 sari  
**Province**  
 Mazandaran  
**Postal code**  
 4847191971  
**Phone**  
 +98 21 2624 3467  
**Email**  
 nazanin.yousefi.72@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Results from clinical trials

### When the data will become available and for how long

6Month after print results

### To whom data/document is available

for researchers working in Mazandaran University of Medical Sciences

### Under which criteria data/document could be used

Use of results is allowed only with the mention of the source

### From where data/document is obtainable

nazanin.yousefi.72@gmail.com

### What processes are involved for a request to access data/document

Request from the researcher

### Comments

If you have sufficient conditions and check the request of people who want to buy the project, they will be examined