

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
Phone
 +98 11 3354 2472
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
 farah abad street
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