Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of anti-inflammatory effects of curcumin which is encapsulated by niosomal nano-carrier in lesional skin of psoriatic patient: A pilot and clinical trial study

Protocol summary

Study aim
Evaluation of anti-inflammatory effects of encapsulated curcumin by niosomal nano-carrier in lesional skin of psoriatic patient

Design
Randomized, double-blind, placebo-controlled clinical trial in 10 patients (paired lesions)

Settings and conduct
The physician select patients at the skin clinic and medical pictures would be taken from skin lesion before and after treatment with drug and placebo for assessment of local disease severity. At the end of treatment skin punches are taken from the patients and then immune cells accumulation and also specific genes expression were evaluated by real time PCR. Blinding will be performed for patients, physician, and experimenter.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Paired lesional skin of psoriatic patient with any infection or malignancy older than18 years
Exclusion criteria: pregnancy and lactation, suffering any other autoimmune and inflammatory disease

Intervention groups
The intervention group will apply the nano-curcumin ointment in specified lesional skin daily for four weeks and paired lesion of the same patients will apply a placebo in the same period for comparison of drug efficacy. Drug and placebo ointments would be constructed with the same features by a pharmacologist.

Main outcome variables
Expression of genes Ki67, βdefensin2, S100A12, S100A7, TNFα, IL23, IL22, IL17; Assessment of local disease severity; Immune cells accumulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181217042030N1**
Registration date: **2019-05-01, 1398/02/11**
Registration timing: **prospective**

Last update: **2019-05-01, 1398/02/11**
Update count: **0**

Registration date
2019-05-01, 1398/02/11

Registrant information

Name
Ali Memarian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of anti-inflammatory effects of curcumin which is encapsulated by niosomal nano-carrier in

lesional skin of psoriatic patient: A pilot and clinical trial study

Public title
The therapeutic effect of nano-Curcumin on skin lesion of psoriasis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Parallel lesional skin of Psoriatic patient lesions from mild or severe form of disease Age >+18 Signing the informed consent form
Exclusion criteria:
Pregnant and lactation Suffering from autoimmune or other inflammation diseases Suffering from Cirrhosis and Hepatic disease Suffering from Metabolic syndrome Suffering from severe Renal disease Allergic reaction to Curcumin
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
Skin punches from parallel and similar lesions in different area of body
Randomization (investigator's opinion)
Randomized
Randomization description
Since the patient lesions will be the study units and eligible patients have two similar lesions, one lesions will receives one of the interventions and the other comparison. By using a Randomizer software, on set of random numbers (i.e.1 to 10) will be generated. patient with odd number will receive intervention treatment on right lesion and comparison treatment on left lesion and patients with even number will receive intervention treatment on left lesion and comparison treatment on right lesion.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study blinding would be performed for patients and also for persons which do sampling and experiment. Randomization would be done by one colleague. Drug and placebo ointments would be applied for patients as a left or right drug, after taken an informed consent. Patients and the sampler (specialist) are not aware which treatments are received because drug and placebo would have same features and sampling will be done in the same way. Finally, researchers will receive samples only with the codes.
Placebo
Used
Assignment
Parallel
Other design features
This is a full-matched clinical trial study with with-in patient (internal) comparison group and the study unit are Lesions instead of patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Shast-Kola road
City
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Province
Golestan
Postal code
4934174515
Approval date
2019-03-04, 1397/12/13
Ethics committee reference number
IR.GOUMS.REC.1397.275

Health conditions studied

1

Description of health condition studied
Psoriasis
ICD-10 code
L40.0
ICD-10 code description
Psoriasis vulgaris

Primary outcomes

1

Description
IL23 gene expression
Timepoint
4 weeks after local treatment with encapsulated curcumin by noisome
Method of measurement
Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

2

Description

IL17 gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

3

Description

TNFα gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

4

Description

IL22 gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

5

Description

s100A7 gene expresion

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

6

Description

s100A12 gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

7

Description

βefensin2 gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

8

Description

Ki67 gene expression

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Real time PCR and evaluating of gene expression exchange to control gene (18sRNA)

9

Description

Accumulation of immune cells in lesional skin tissue

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

H&E staining and optical microscopy

10

Description

Local disease severity

Timepoint

4 weeks after local treatment with encapsulated curcumin by noisome

Method of measurement

Observation by physician

Secondary outcomes

1

Description

Side effects (systemic and local)

Timepoint

A phone number were given to patients for any emmergency call during treatment. Patient could report any side effects 24/7 as well as during follow-ups, all the way through the treatment and after completion

Method of measurement

Medical examination by the consultant dermatology

Intervention groups

1

Description

Intervention group: patients were instructed to apply the niosome-curcumin ointment of 5 micromolar curcumin once a day for 4 weeks on their eligible skin lesions

Category

Treatment - Drugs

2

Description

Comparison group: patients were instructed to apply the placebo ointment (curcumin without niosome) once a day for 4 weeks on eligible skin lesions

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Beauty Clinic

Full name of responsible person
Fatemeh Livani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Gorgan 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
Golestan University of Medical Sciences

Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available