

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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 than 18 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,  $\beta$ defensin2, S100A12, S100A7, TNF $\alpha$ , 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3245 1644

##### Email address

alimemarian@goums.ac.ir

#### 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 science

**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**

Gorgan

**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 noise

**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 niosome

**Method of measurement**

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

**3**

**Description**

TNF $\alpha$  gene expression

**Timepoint**

4 weeks after local treatment with encapsulated curcumin by niosome

**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 niosome

**Method of measurement**

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

**5**

**Description**

s100A7 gene expression

**Timepoint**

4 weeks after local treatment with encapsulated curcumin by niosome

**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 niosome

**Method of measurement**

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

**7**

**Description**

$\beta$ efensin2 gene expression

**Timepoint**

4 weeks after local treatment with encapsulated curcumin by niosome

**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 niosome

**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 niosome

**Method of measurement**

H&E staining and optical microscopy

**10**

**Description**

Local disease severity

**Timepoint**

4 weeks after local treatment with encapsulated curcumin by niosome

**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 emergency 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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Fourth floor, Iranian building, Edalat 15, Valiasr avenue

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad-Reza Honarvar

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Deputy of research and Technology, Shast-Kola road, Golestan University of Medical Sciences, Gorgan

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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**

Hanieh Kolahdooz

**Position**

MS.c Student of Medical Immunology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Immunology

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

Ali Memarian

**Position**

Assistant Professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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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