Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluate the safety, side effects and maximum tolerable dose of topical application of Antimicrobial Peptides: Pexiganan (MSI-78), Tilapia piscidin 4 (TP4), Melittin, Nisin-A and Omiganan (MX-226) on the skin of healthy volunteers to the treatment of Skin and Soft Tissue Infections.

Protocol summary

Study aim

Evaluate the safety, side effects and maximum tolerable dose of 5 Antimicrobial Peptides (AMPs) on the skin of healthy volunteers to the treatment of Skin and Soft Tissue Infections.

Design

Double-blind block randomized, vehicle-controlled, ascending doses clinical trial phase 1with 30 patients in 5 groups. Concealed randomization sequence carried out with sequentially numbered, sealed, opaque envelopes.

Settings and conduct

Initially, 30 healthy volunteers who have Inclusion criteria will be randomly divided into five groups of six. In each group, 4 intervention subjects will be treated with the topical single dose AMPs on their healthy skin and 2 control subjects will receive placebo. The intervention groups will receive 1/2, 1, 2, 3 and 4fold of the minimum inhibitory concentration (MIC) of peptides, respectively. During the study, safety, side effects and maximum tolerable dose of peptides will be examined. The place of study is in Imam Reza Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participant compliance with treatment method (Adherence) Having conditions for frequent visits to control the treatment method Informed consent to participate in the research project Non-smoker (no nicotine products for at least 3 months prior to screening) BMI ≥18 kg/m2 and ≤32.0 kg/m2 with a minimum weight of 50 kg Exclusion criteria: Use of any antibiotic and traditional drugs at least 7 days prior to screening Use of immunosuppressive drugs at least 14 days prior to screening Having any history of skin allergies

Intervention groups

The intervention groups will be treated with different concentrations of AMPs and the control groups will receive a placebo.

Main outcome variables

The safety of local use of antimicrobial peptides, The maximum tolerable concentration of topical antimicrobial peptides

General information

Reason for update

In the section on how to conduct the study, the duration of the treatment was 21 days with an interval of every 3 days. Considering that the main purpose of the first phase of a clinical trial is to check the safety of the investigational medicinal product in healthy people, not treatment and effectiveness, the subjects of the present study were not sick. Therefore, the duration of treatment is not considered. For this purpose, the design of a study in the field of measuring the time points of the primary outcome variable in the form of a single ascending dose on the skin of healthy people with the measurement time points at 30 and 60 minutes after the intervention (to assess immediate sensitivity) and at 24 and 72 The hour after the intervention (to assess delayed sensitivity), needs to be updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190924044863N1**
Registration date: **2020-06-20, 1399/03/31**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **1**

Registration date

2020-06-20, 1399/03/31

Registrant information

Name

Kiarash Ghazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the safety, side effects and maximum tolerable dose of topical application of Antimicrobial Peptides: Pexiganan (MSI-78), Tilapia piscidin 4 (TP4), Melittin, Nisin-A and Omiganan (MX-226) on the skin of healthy volunteers to the treatment of Skin and Soft Tissue Infections.

Public title

Evaluate the safety, side effects and maximum tolerable dose of 5 Antimicrobial Peptides on the skin of healthy volunteers to the treatment of Skin and Soft Tissue Infections.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient compliance with treatment method (Adherence) Having conditions for frequent visits to control the treatment method Informed consent to participate in the research project Non-smoker (no nicotine products for at least 3 months prior to screening) BMI ≥18 kg/m2 and ≤32.0 kg/m2 with a minimum weight of 50 kg

Exclusion criteria:

Use of any antibiotic within 7 days before entering the study Use of traditional treatments within 7 days before entering the study Use of immunosuppressive drugs within 14 days before entering the study Having any history of skin allergies

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Block randomization Randomization Unit: Block size of 6 Randomization Tool: Random number table using http://www.randomization.com Random sequence generation: Random number table Allocation concealment: Sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind. So that the participants, clinicians and evaluators will be unaware of intervention and control groups. In other words, participants, physicians, safety & side effect evaluators and laboratory personnel will not know which participant is taking the drug and which of them is taking the placebo. For this purpose, the drug/placebo will be placed in sequentially numbered, sealed, opaque envelopes and will be assigned to each participant with a random selection.

Placebo

Used

Assignment

Parallel

Other design features

This study has been designed in phase 1, double-blind, vehicle-controlled, randomized ascending doses trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Research Chancellor, Mashhad University of Medical Sciences, In front of Daneshgah No. 18 Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9919991766

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.MUMS.REC.1398.154

2

Ethics committee

Name of ethics committee

Ethics committee of National Institute for Medical Research Development (NIMAD)

Street address

National Institute for Medical Research Development (NIMAD), No.21, At the beginning of Besat Ave.,Western Fatimi Street.

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Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.NIMAD.REC.1398.248

Health conditions studied

1

Description of health condition studied

Skin and soft tissue infections

ICD-10 code

L00-L08

ICD-10 code description

Infections of the skin and subcutaneous tissue

Primary outcomes

1

Description

Evaluate the safety of topical application of Antimicrobial Peptides (AMPs)

Timepoint

The time periods of investigation of the safety of the investigational medicinal product: the results will be evaluated at 30 and 60 minutes after the intervention (to evaluate immediate sensitivity) and at 24 to 72 hours after the intervention (to evaluate delayed sensitivity).

Method of measurement

Medical examination of participants and perform clinical and laboratory tests based on the guideline for Safety Monitoring of Clinical Trial

2

Description

Calculate the maximum tolerable dose of topical application of Antimicrobial Peptides (AMPs)

Timepoint

During the study, it will be variable according to the maximum tolerable dose of peptides.

Method of measurement

The maximum tolerable dose of peptides that were safe and have no side effects.

Secondary outcomes

1

Description

Evaluation of adverse effects based on Safety Monitoring Protocol in Clinical Trial

Timepoint

The time periods of investigation of the safety of the investigational medicinal product: the results will be evaluated at 30 and 60 minutes after the intervention (to evaluate immediate sensitivity) and at 24 to 72 hours after the intervention (to evaluate delayed sensitivity).

Method of measurement

Estimating the grade of severity (grade 1 to 4) based on Safety Monitoring Protocol in Clinical Trial

Intervention groups

1

Description

Intervention group: This group will receive the antimicrobial peptides of the present study as a single local dose. The amount of consumption will be with concentrations 1.2 to 4 times the minimum inhibitory concentrations (MIC) in the form of a single ascending dose in 5 groups. Its consumption amount will be enough to cover at least one square inch of the skin surface. The amount and frequency of drug/placebo consumption will be the same in the control and intervention groups.

Category

Treatment - Drugs

2

Description

Control group: This group will receive a single local dose of placebo. Its consumption amount will be enough to cover at least one square inch of the skin surface. The amount and frequency of drug/placebo consumption will be the same in the control and intervention groups.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

Mahdi Kouhi

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Qaem Hospital, Ahmadabad Ave., Dr. Ali Shariati Square

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2

Recruitment center

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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http://v-research.mums.ac.ir/index.php

Grant name
Grant of Dr. Kiarash Ghazvini: Project No 971595

Grant code / Reference number
971595

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
National Institute for Medical Research Development (NIMAD)

Proportion provided by this source
90

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
Mashhad University of Medical Sciences

Full name of responsible person
Mahdi Kouhi

Position
Ph.D Student of Medical Bacteriology

Latest degree
Master

Other areas of specialty/work
Microbiology

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Person responsible for scientific inquiries

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Kiarash Ghazvini

Position
Associate professor

Latest degree

Ph.D.

Other areas of specialty/work
Microbiology

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Person responsible for updating data

Contact

Name of organization / entity
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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
Not applicable