Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of immunothrapeutic g2 vaccine on treatment of oral lichen planus

Protocol summary

Summary

Effect of immunotherapeutic G2 vaccine on Oral lichen planus(OLP) The purpose of this study was to evaluate the efficacy of G2 vaccine on treatment of OLP pateints reffered to department of oral medecine ,faculty of dentistry, tehran university of medical sciences. patients with atrophic-erosive lichen planus were included in this study. Patients with systemic disease,pregnant and breast feeding women were excluded from the study. Ten OLP patients (7 female, 3 male) were enrolled in this study. Diagnosis of OLP was on the basis of clinical criteria and histological study. Patients received subcutaneous injection of 0.4 cc of G2 vaccine, once a week for twelve weeks. Oral symptoms before and after treatment assessed by visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810112950N1**
Registration date: **2010-04-14, 1389/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-04-14, 1389/01/25

Registrant information

Name
Sayed Javad Kia
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 13 1323 0775
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djavadkia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran Medical Science University

Expected recruitment start date

2003-11-21, 1382/08/30

Expected recruitment end date

2004-07-20, 1383/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of immunothrapeutic g2 vaccine on treatment of oral lichen planus

Public title

The effect of immunothrapeutic g2 vaccine on treatment of oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:atrophic-erosive oral lichen planus
Exclution criteria:systemic disease-breast feeding and pregnant weman-use of corticosteroids in the last month

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
clinical trial before after

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Vice Chancelor for research

Street address
Valiasr Ave-Dameshgh St-no 23

City
Tehran

Postal code
14167

Approval date
empty

Ethics committee reference number
130/6052

Health conditions studied

1

Description of health condition studied
Oral Lichen Planus

ICD-10 code
L00-L99

ICD-10 code description
Other Lichen Planus

Primary outcomes

1

Description
Pain and burning sensation asking from pateints

Timepoint
Once a week for 12 weeks

Method of measurement
Visual analoge scle-0=no pain and burning and 10 the most pain and burning

2

Description
CD4 and CD8 count

Timepoint
before injections-end of injections(13th week)

Method of measurement
number of CD4 and CD8 in peripheral blood(by flowcytometry)

Secondary outcomes

1

Description
Treatment oral lichen planus lesions(reduce size of lesions)

Timepoint
Before injection-sixth week-twelveth week

Method of measurement
Ruler(mm2)

Intervention groups

1

Description
Immunotherapeutic G2 vaccine -Ampule 0.4 cc -sub cutaneous injection in deltoid region once a week for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Oral Medecine Department,School of Dentistry,Tehran University

Full name of responsible person
Dr Sayed Javad Kia

Street address
Enghelab Ave,Ghods Ave

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dr Mohaghegh Biotechnology Reaserch Center

Full name of responsible person
Dr Saleh Mohaghegh Hazrati

Street address
Tehran-Mail box 13155-148

City
Tehran

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr Mohaghegh Biotechnology Reaserch Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty