Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Effect of tacrolymus on chronic allergic conjunctivitis

Protocol summary

Summary
Aim: The aim of this study is to evaluation the Effect of tacrolymus on chronic allergic conjunctivitis. This study is a randomized block, single blind design and is in Phase II clinical trial. Inclusion criteria is Allergic conjunctivitis and Exclusion criterias are Blepharitis, Follicular blepharitis, Iritis, Eye infection and Evidence of herpes infection in the past. 126 patients will be studied. In first group patient will receive standard treatment that consist of topical mast cell stabilizer, corticosteroid and NSAID. In second group tacrolimus will be added to standard treatment. Primary outcomes are decrease pruritus, erythema, pain and Foreign body sensation in the eye.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201409248410N3**
Registration date: **2014-10-08, 1393/07/16**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2014-10-08, 1393/07/16

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Arak University of Medical Sciences

Expected recruitment start date
2011-07-20, 1390/04/29
Expected recruitment end date
2012-09-19, 1391/06/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of tacrolymus on chronic allergic conjunctivitis

Public title
Effect of tacrolymus on allergic conjunctivitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:1. Allergic conjunctivitis. Exclusion criteria:1.Blepharitis 2.Follicular blepharitis 3.Iritis 4.Eye infection 5.Evidence of herpes infection in the past
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded

Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the arak university of medical sciences
Street address
Arak University of Medical Sciences, Alamolhoda Ave
City
Arak
Postal code
Approval date
2011-06-22, 1390/04/01
Ethics committee reference number
90-109-13

Health conditions studied

1

Description of health condition studied
chronic allergic conjunctivitis
ICD-10 code
H10.4
ICD-10 code description
chronic conjunctivitis

Primary outcomes

1

Description
Eye pruritus
Timepoint
every week until one month then every month until 3 months
Method of measurement
VAS criteria

2

Description
Eye Erythema
Timepoint
every week until one month then every month until 3 months
Method of measurement
slit lamp exam

3

Description
Foreign body sensation
Timepoint
every week until one month then every month until 3 months
Method of measurement
VAS criteria

Secondary outcomes

1

Description
eye pain
Timepoint
every week until one month then every month until 3 months
Method of measurement
VAS criteria

2

Description
Ptosis
Timepoint
every week until one month then every month until 3 months
Method of measurement
VAS criteria

Intervention groups

1

Description
In control group patient will treat by Flucort Eye Drops every 6h and ketotifen eye drop every 12h and Dicloptin eye drop every 12h for 3 months.
Category
Treatment - Drugs

2

Description
In intervention group in addition to standard treatment in control group, patient will use topical tacrolimus with low thickness on the back of eyelids every night until a week then every 12h until 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Emam reza clinic
Full name of responsible person
Dr ahmad Sarvarian

Street address
City
arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences, Vice chancellor for research
Full name of responsible person
dr Ali Asghar Yaghoobi
Street address
Arak University Of Medical Sciences, Basij Square
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences, Vice chancellor for research
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
Arak university of medical sciences
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Ophthalmologist, Assistant Professor
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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