Evaluation of the therapeutic effects of Mesalazine in patients with chronic idiopathic urticaria

Protocol summary

Summary
The Goal of this open clinical trial is to evaluate the effect of Mesalazine on Chronic Idiopathic Urticaria. 30 patients are selected randomly. The patients include new cases and resistant cases to Antihistamines. We exclude children under 12 years old, pregnant and breastfeeding mothers, those with sensitivity to this medication and those with underlying problems. After performing CBC, LFT, BUN, Cr, Stool Exam and TFT, Mesalazine 500 mg Bid is administered to the patients and they would be followed after 15 and 60 days. The primary outcome is decrease in symptoms and improvement in quality of life of the patients according to the indices recorded. If any improvement observed in first 15 days of treatment, the drug would be discontinued.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138710041520N1
Registration date: 2009-04-03, 1388/01/14
Registration timing: registered_while_recruiting

Last update: Update count: 0
Registration date 2009-04-03, 1388/01/14

Registrant information
Name
Alireza Abdollahee
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Recruitment status
Recruitment complete

Funding source
Vice-chancellor for Research of Shiraz University of Medical Sciences

Expected recruitment start date 2008-06-26, 1387/04/06
Expected recruitment end date 2009-05-22, 1388/03/01
Actual recruitment start date empty
Actual recruitment end date empty
Trial completion date empty

Scientific title
Evaluation of the therapeutic effects of Mesalazine in patients with chronic idiopathic urticaria

Public title
Mesalazine in chronic idiopathic urticaria

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: new cases, the patients without proper control with antihistamines Exclusion Criteria: children under 12y, pregnant ladies or women with breast feeding, underlying diseases, 5-ASA sensitivity, G6PD deficiency

Age
From 12 years old to 75 years old

Gender
Both

Phase
2

Groups that have been masked
None

Sample size
Target sample size: 30

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features
30 patients with chronic idiopathic urticaria for more than 6 weeks, without any etiologic finding in lab tests and examinations, include in the research.

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Shiraz University Of medical sciences
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Postal code
Approval date
2008-06-24, 1387/04/04
Ethics committee reference number
2954

Health conditions studied

1
Description of health condition studied
Chronic Idiopathic urticaria
ICD-10 code
L50.1
ICD-10 code description
Idiopathic Urticaria

Primary outcomes

1
Description
Decrease in Symptoms of the patients
Timepoint
15 dayas and 1 month and 2 month
Method of measurement
Symptom Severity indices and Quality of Life Questionaire

Secondary outcomes

1
Description
Improvement in Quality of Life of the patients
Timepoint
2 month

Method of measurement
Quality of life Questionaire

Intervention groups

1
Description
Mesalazine 500 mg Bid for 2 months
Category
empty

Recruitment centers

1
Recruitment center
Name of recruitment center
Dermatology Clinics - Shiraz Faghihi Hospital
Full name of responsible person
Street address
City

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Shiraz University of Medical Sciences - Vice Chancellor for Research Affairs
Full name of responsible person
Dr. Mohammad Hosein Dabaghmanesh
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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
Shiraz University of Medical Sciences - Vice Chancellor for Research Affairs
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

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Person responsible for updating data

Contact
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