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: 0
Registration date 2009-04-03, 1388/01/14

Registrant information
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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
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
89665
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 days 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
Person responsible for general inquiries

| Contact | 
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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 |