Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of therapeutic effect of oral N-Acetyl Cystein in comparison with placebo in patients diagnosed as subacute sinusitis, a double blind placebo controlled randomized clinical trial

Protocol summary

Summary

The objective of this study was to investigate the therapeutic effect of oral N-Acetyl Cysteine (NAC) in the treatment of subacute sinusitis. 45 patients, aged 18 years old or more who had subacute sinusitis were enrolled in this randomized trial. All patients received Co-Amoxiclav (Amoxicillin 500 mg and Clavulanic acid 125mg Q8h, orally), pseudoephedrine (60mg three times a day, orally), and Sodium chloride irrigation for two weeks. In addition, patient received N-Acetyl Cysteine (6oo mg, three times a day, orally) in the intervention group but placebo in the control group during the treatment period (two weeks). Signs and symptoms of the disease, using Snat 20 questionnaire, paranasal sinus involvement, using PNS CT Scan and the results of nasal secretion cultures were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806112406N1**
Registration date: **2010-01-27, 1388/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-27, 1388/11/07

Registrant information

Name

Mehrzad Bahtouee

Name of organization / entity

Boushehr University of Medical Sciences, School of Medicine

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Recruitment status

Recruitment complete

Funding source

Research management center, Bushehr University of Medical Sciences

Expected recruitment start date

2008-11-19, 1387/08/29

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of oral N-Acetyl Cystein in comparison with placebo in patients diagnosed as subacute sinusitis, a double blind placebo controlled randomized clinical trial

Public title

Therapeutic effect of oral NAC on Sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of subacute sinusitis according to signs and symptoms 3 weeks to 3 months and signs of sinusitis in CT scan Exclusion criteria: Presence of allergic rhinitis, asthma, pregnancy, diabetes mellitus, transplantation, CRF, chronic alcoholism, severe malnutrition, AIDS, Down syndrome, history of migraine,

HTN, BPH, consumption of antidepressants, Methyl dopa, Propranolol, or Warfarin, history of kidney stone, or liver disease, more than 60 years old age, drivers, or pilots

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research managment center, Bushehr University of Medical Sciences

Street address
Research managment center, Bushehr University of Medical Sciences, Moallem street, Bushehr

City
Bushehr

Postal code

Approval date
2010-06-10, 1389/03/20

Ethics committee reference number
1643/3/18/20/دپ

Health conditions studied

1

Description of health condition studied
subacute Sinusitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Culture of nasal secretion

Timepoint
1 month after competement of treatment

Method of measurement
microbiological culture

2

Description
Signs and symptoms of disease

Timepoint
1 day after completement of treatment

Method of measurement
face to face completement of Snot 20 questionnaire by a physician

3

Description
involvement of paranasal sinuses

Timepoint
1 month after competement of treatment

Method of measurement
CT scan, cure rate of sinusitis according to Lund-Mackay score

Secondary outcomes

1

Description
clinical improvement

Timepoint
1 day and one month after copletement of treatment

Method of measurement
snot20 questionaire

2

Description
Radiological improvement in paranasal CT scan

Timepoint
1 month after completment of treatment

Method of measurement
Lund-Mackey score

Intervention groups

1

Description
Co-Amoxiclav (Amoxicillin 500 mg and Clavulanic acid 125mg Q8h, orally), pseudoephedrine (60mg three times a day, orally), and Sodium chloride irrigation plus N-Acetyl Cysteine (6oo mg, three times a day, orally) for two weeks.

Category
Treatment - Drugs

2

Description
Co-Amoxiclav (Amoxicillin 500 mg and Clavulanic acid 125mg Q8h, orally), pseudoephedrine (60mg three times a day, orally), and Sodium chloride irrigation plus placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The outpatient clinic of Bushehr University of medical sciences
Full name of responsible person
Dr. Gholam_Hosein Monavvar_Sadegh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research managment center of Bushehr University of Medical Sciences
Full name of responsible person
Dr. Keivan Zandi
Street address
Research managment center, Bushehr University of medical sciences, Moallem street, Bushehr
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Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research managment center of Bushehr University of Medical Sciences
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
Bushehr University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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