

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 (600 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

Country

Iran (Islamic Republic of)

Phone

+98 77 1252 4044

Email address

mbahtouee@bpums.ac.ir

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 management center, Bushehr University of Medical Sciences

Street address

Research management 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/پد

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 completion of treatment

Method of measurement

microbiological culture

2

Description

Signs and symptoms of disease

Timepoint

1 day after completion of treatment

Method of measurement

face to face completion of Snot 20 questionnaire by a physician

3

Description

involvement of paranasal sinuses

Timepoint

1 month after completion 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 completion of treatment

Method of measurement

snot20 questionnaire

2

Description

Radiological improvement in paranasal CT scan

Timepoint

1 month after completion 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 (600 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

Street address

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research management center of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Keivan Zandi

Street address

Research management center, Bushehr University of medical sciences, Moallem street, Bushehr

City

Bushehr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research management 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

Full name of responsible person

Dr. Gholam_Hosein Monavvar_Sadegh

Position

General physician

Other areas of specialty/work

Street address

Medical Faculty, Bushehr University of Medical Sciences, Moallem street

City

Bushehr

Postal code

Phone

+98 77 1252 4044

Fax

Email

dr.monavarsadegh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences, Medical Faculty

Full name of responsible person

Dr. Mehrzad Bahtouee

Position

Assistant Professor of Internal Medicine

Other areas of specialty/work

Street address

Medical Faculty, Bushehr University of Medical Sciences, Moallem street

City

Bushehr

Postal code

Phone

+98 77 1252 4044

Fax

Email

mbahtouee@bpums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medical Faculty, Bushehr University of Medical Sciences

Full name of responsible person

Hesam_oddin Maneshi

Position

Medical Student

Other areas of specialty/work

Street address

Medical Faculty, Bushehr University of Medical Sciences, Moallem street

City

Bushehr

Postal code

Phone

+98 77 1252 4044

Fax**Email**

h_maneshi@bpums.ac.ir

Web page address**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