Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of N-acethylcystein on pain after laparascopic cholecystectomy

Protocol summary

Summary

This research is done to examine the effect of N-acethylcystein on postoperative pain after laparascopic cholecystectomy. This research is randomized double blind controled clinical trial. Thirty patients with this inclusion criteria: 20-50 years old; candidate for laparascopic cholecystectomy; with ASA1(healthy patient without other disease) are selected and randomly divided in two groups. Exclusion criteria include previous abdominal surgery; known sensivity to N-acethylcystein; operation time more than two hours; any uncommon complication in surgery or in intubation; neuropsychiatric disease; chronic pain before surgery; addiction; pregnancy; lactation and other concurrent surgery. The used substance is N-acethylcysteine, its chemical compound is Acetamido-3-sulfanylpropanoic acid (C5H9NO3S) and is acethylated derivative of L-cysteine amino acid. The night before surgery, 1200mg oral N-acethylcysteine in the form of two effervescent tablets (600mg) dissolved in water, were given to the intervention group and the morning before operation, 3cc of intravenous N-cethylcystein(200mg/cc) that was equal to 600 mg, in 100cc normal saline in a 5 minute transfusion . The prescribtion duration is twice, the night before and the morning of surgery and no longer required to be prescribed. For the control group, two vitamin c effervescent tablets (placebo) dissolved in water, were given at night before surgery and 3cc distilled water in 100cc normal saline as placebo transfused in 5 minutes in the morning before surgery.The liquid volume in all syringes specified as number 1 and number 2 with 3cc fluid, only the researcher's colleague knows about this and to avoid observer bias, in double-blind study. The anesthesia plan is similar in all of the cases including premedication, induction, antiemetic (plasil), volatile anesthetics and administration of morphine (1mg/kg). Mechanical ventilation is set to low tidal volume (6-8 cc/Kg) and high respiratory rate (14-16/minute) to prevent chest pain(confounding factor) caused by ventilation of small lung. Small lung in laparascopy is induced by insufflation of Co2 into the abdominal cavity and its resulted low lung functional residual capacity . The blood pressure, heart rate, occurrence of nausea and vomiting and severity of pain (by visual analog scale) are evaluated during postoperative recovery consecutively 1, 2, 4, 8 and 12 hours after the surgery. The total amount of pethidine consumed within 24 hours after surgery in two groups is evaluated and compared. If the pain score is more than 5, 30 milligrams of pethidine is administered each 4 to 6 hours. The total duration of the study is 12 months. Results: The study findings show a reduction of pain, the need for opioid and less side effects. Other outcoms studied are The existing nausea, vomiting and blood pressure and pulse rate alterations after the surgery, in the above-mentioned intervals, and decrease the use of this drug to reduce pain and decline in using of pethidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112120020N1**
Registration date: **2015-10-28, 1394/08/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-28, 1394/08/06

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Babol University of Medical Science

Expected recruitment start date
2015-07-23, 1394/05/01
Expected recruitment end date
2016-04-20, 1395/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of N-acethylcystein on pain after laparascopic cholecystectomy

Public title
The effect of N- acethylcystein on pain treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 20-50 years old; candidate for laparascopic cholecystectomy; ASA class1(healthy patient without other disease). Exclusion criteria: previous abdominal surgery; known sensitivity to N-acethylcystein; operation time more than 2 hours; any uncommon complication in operation or in intubation; chronic pain before operation; neuropsychiatric disease; addiction; pregnancy; lactation and other concurrent surgery.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Vice chancellor for research, Babol University of Medical sciences
Street address
Ganjafrooz street, Babol
City
Babol
Postal code
Approval date
2015-06-23, 1394/04/02
Ethics committee reference number
305670

Health conditions studied

1

Description of health condition studied
pain after laparascopic cholecystectomy
ICD-10 code
k80.2
ICD-10 code description
calculus of gallbladder without cholecystitis

Primary outcomes

1

Description
pain
Timepoint
in recovery and 1, 2, 4, 8, 12 and 24 hours after operation
Method of measurement
visual analog scale(VAS)

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
In recovery and 1, 2, 4, 8, 12 and 24 hour after operation
Method of measurement
scale 0-4

Intervention groups

1

Description
The night before surgery, 1200mg oral N-acethylcysteine in the form of two effervescent tablets (600mg)dissolved in water were given to the intervention group and the morning before operation, 3cc of intravenous N-

cethylcystein(200mg/cc) that was equal to 600 mg in 100cc normal saline in a 5 minute transfusion was injected to intervention group. The prescribtion duration is twice the night before and the morning of surgery and no longer required to be prescribed.

Category

Treatment - Drugs

2

Description

For the control group, two vit c effervescent tablets (placebo) dissolved in water, were given at night before surgery and 3cc distilled water in 100cc normal saline as placebo transfused in 5 minutes in the morning before surgery.The liquid volume in all syringes specified as number 1 and number 2 with 3cc fluid, only the researcher's colleague knows about this and to avoid observer bias, in double-blind study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mrs Shahrbanoo Khatami

Street address

Shahid Keshvari Bridge,Shahid Beheshti Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Science

Full name of responsible person

Dr Ali Bijani

Street address

Babol University of Medical Scince, Ganjafrooz Street, Babol

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Babol University of Medical Science

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

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Full name of responsible person

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Other areas of specialty/work

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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