

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of short term ibuprofen on NGAL level in dysmennorrhea, a pilot study

Protocol summary

Study aim

investigation of acute ibuprofen ingestion on acute kidney damage

Design

Twenty dysmenorrhea patients will be divided into two groups. In group one, ten patients will receive 400 mg ibuprofen capsules every 8 hours for one day. Group two will receive placebo capsules with the same protocol. Blood samples will be withdrawn before intervention and 12 hours after intervention.

Settings and conduct

Dysmenorrhea volunteers will be recruited in Qom city. They are blind about the intervention. Blinding and package coding will be conducted by the investigator.

Participants/Inclusion and exclusion criteria

20 dysmenorrhea with healthy kidneys

Intervention groups

Two groups; Group one will receive ibuprofen and Group two will receive placebo

Main outcome variables

Change neutrophil gelatinase-associated lipocalin (NGAL) biomarker level

General information

Reason for update

Acronym

NGAL

IRCT registration information

IRCT registration number: **IRCT20191205045614N1**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name

Kowsar Marefat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3771 4869

Email address

kowsarmarefat@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-23, 1399/03/03

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of short term ibuprofen on NGAL level in dysmennorrhea, a pilot study

Public title

Effects of short term ibuprofen on neutrophil NGAL level in dysmennorrhea, a pilot study

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Dysmenorrhea

Exclusion criteria:

History of renal dysfunction

Age

From **13 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Before and after menstruation blood samples withdrawn

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients will receive packages containing three capsules.

Patients are not aware of the content. Capsules was

packaged and coded by the investigator.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Azad Tehran University of
Medical Sciences

Street address

Ghods Town (West), between South Flamek and
Zarafshan, Iran TV Street - Headquarters of the
Ministry of Health, Treatment and Medical Education,
Block A, 13th floor

City

Tehran

Province

Tehran

Postal code

ethics.research.ac.i

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.IAU.PS.REC.1398.294

Health conditions studied**1****Description of health condition studied**

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes**1****Description**

NGAL biomarker level

Timepoint

Before and 12h after consumption of 1200 mg of
ibuprofen

Method of measurement

NGAL ELISA kit

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Group 1 including 10 randomly
assigned patients. They will receive 400mg ibuprofen
capsules every 8 hours for 24 hours. Before intervention
and 12 hours after intervention blood samples will be
withdrawn.

Category

Treatment - Drugs

2**Description**

Control group: Intervention group: Group 2 including 10
randomly assigned patients. They will receive placebo
capsules every 8 hours for 24 hours. Before intervention
and 12 hours after intervention blood samples will be
withdrawn.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Danesh laboratory

Full name of responsible person

Kowsar Marefat

Street address

1th Floor, No. 19, 10th Alley, 19 Dey Ave

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3713615759

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

District 1, Yakhchal Street, Yasaman Alley

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fhashemian@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

azad islamic university

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available