

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Ginger in increasing endometrial thickness among the referred infertile female IUI candidates with thin endometrium to infertility department of Yas Hospital

Protocol summary

Study aim

In a double blind randomized clinical trial 155 patients in the Case group receive Ginger 250 mg tablets once a day for a month before IUI cycle, meanwhile the Control group receives placebo. On the first day of the next menstrual cycle, ovulation induction is started by letrozole for 5 days along with 3 HMG 75mg /daily. Endometrial thickness is measured via vaginal ultrasound when mature follicles are >18mm. rhCG 250µg for trigger is then injected. IUI is done 36 hours later for both groups. chemical pregnancy is confirmed by positive BhCG at day 14 after the trigger. Clinical pregnancy is confirmed at week 6 by vaginal ultrasound. Then ongoing pregnancy and take-home baby will be evaluated.

Design

Patients who use tablet placebo once a day for one month before IUI cycle(N=155)

Settings and conduct

This randomized double blind placebo Controlled is Conducted at Yas hospital of Tehran University of medical sciences at Ivf Clinic, after informed Consent is Signed by patients, 310 patients randomly assigned in Case or Control group. Patients & physicians are blinded regarding groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are Candidate for IUI with endometrial thickness<7mm in vaginal ultrasound; at least one patent tube at hystero Salpingography
Exclusion criteria: hypertension;diabetes; any underlying or endocrinological disease; hypersensitivity to ginger; age>40y; AMH <1

Intervention groups

Patients who use tablet ginger 250mg once a day for one month before IUI cycle(N=155)

Main outcome variables

positive BhCG at 14th day after IUI; visualisation of fetal

heart at 6 weeks in vaginal ultrasound; ongoing pregnancy; take home baby

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N23**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-16, 1400/11/27

Expected recruitment end date

2022-10-19, 1401/07/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginger in increasing endometrial thickness among the referred infertile female IUI candidates with thin endometrium to infertility department of Yas Hospital

Public title

The effect of Ginger on endometrial thickness in IUI cycle with thin endometrium

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are Candidate for IUI with endometrial thickness<7mm in vaginal ultrasound At least one tubal patency at hSG

Exclusion criteria:

Hypertension Diabetes Any endocrinological or underlying disease Hypersensitivity to ginger AMH<1

Age

From **18 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **310**

Randomization (investigator's opinion)

Randomized

Randomization description

In Random allocation rule: First 155 letters A and 155 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (case group) or B (control group) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and physician are blinded regarding drug or placebo

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Tehran University of Medical Science

Street address

Yas Hospital, North Nejatollahi Avenue, karim Khanz and bridge, villa street

City

Tehran

Province

Tehran

Postal code

159781597878

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IRCT. TUMS. MEDICINE. REC. 1400.1332

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

Infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

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

Positive BhCG 14 days after IUI

Timepoint

14 days after IUI

Method of measurement

BhCGmu/dl

Secondary outcomes**1****Description**

Chemical pregnancy

Timepoint

Two weeks after IUI

Method of measurement

BhCG levels

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

Intervention group: Tablet 250mg/day one month before

IUI cycle will be used by patients

Category
Treatment - Drugs

2

Description
Control group: Tablet placebo once daily one month before IUI cycle will be used

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas hospital

Full name of responsible person
Fateme Davari Tanha

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Yas hospital, North nejatollahi avenue, Karimkhan handbridge, Villa street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mis.Mostofi

Street address
Fifth floor, Central building of Tehran University of Medical sciences, Ghods avenue, Keshavarz boulevard

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Grant name

Grant code / Reference number

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

No

Title of funding source
Deputy of research of Tehran University of Medical sciences

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
Tehran University of Medical Sciences

Full name of responsible person
Fateme Davari Tanha

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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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

No - There is not a plan to make this available

Data Dictionary

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