

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of vaginal Danazol versus gonadotropin-releasing hormone agonists in the management of intractable uterine hemorrhage during and post operative hysteroscopy

Protocol summary

Summary

In this study the effect of vaginal Danazol versus gonadotropin-releasing hormone agonists will be compared in the management of intractable uterine hemorrhage during and post operative hysteroscopy. This study will be carried on in Alzahra University Hospital of Tabriz University of Medical Sciences from December 2012 until completing all 144 samples, in a single blind clinical randomized control trial format. All patients with an abnormal moderate uterine bleeding that is resistant to drugs and are candidates for hysteroscopy are randomly divided into two groups by having an informed consent. In first group 400 mg Danazol capsules are used every 12 hours placed into the posterior vaginal fornix. The treatment is administered for 30 day, starting on day 5 of menstruation. In second group intramuscular injection of diphereline 3.75 mg S.R are used before hysteroscopy, starting on day 18 of menstruation every 28 days for 2 month. Duration of hysteroscopy is estimated in minute and amount of uterine hemorrhage during operative hysteroscopy is evaluated by visual scale, which differs from zero (no bleeding) to 5 (sever bleeding). Patients with chronic internal disease, malignant adenexal or uterine pathology, genital tract infections, anticoagulant consumers, and pregnant women are excluded from the study. The primary outcome of this study is amount of intra operative bleeding causing a clear hysteroscopic image, and secondary outcome is duration of the operation, post operative hemorrhage and a successful completed hysteroscopy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307305283N8**

Registration date: **2013-10-22, 1392/07/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-22, 1392/07/30

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3741

Email address

sayyahmellim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vaginal Danazol versus gonadotropin-releasing hormone agonists in the management of

intractable uterine hemorrhage during and post operative hysteroscopy

Public title

The effect of vaginal Danazol in the management of uterine hemorrhage during and post operative hysteroscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women in reproductive age with moderate abnormal uterine bleeding which is resistant to drugs, caused by endometrial hyperplasia; endometrial polyps; submucosal myomas less than 4 cm in size. Exclusion criteria: Patients with Heart, Lung, Renal, Liver disease; Patients with metabolic disease like hypertension, hyperlipidemia, hyperglycemia; Patients with cervical cancers; uterine cancers; submucosal myomas larger than 4 cm in size; Uterine septum; Pregnant women; Patients with genital tract infections; Patients using Anti coagulant drugs; Patients with severe uterine bleeding.

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical sciences, Department of Medicine

Street address

Azadi Avenue, Gholghast street

City

Tabriz

Postal code

5138665793

Approval date

2013-02-17, 1391/11/29

Ethics committee reference number

شماره 91205 و کد اخلاقی 5/4/11092

Health conditions studied

1

Description of health condition studied

abnormal uterine and vaginal bleeding

ICD-10 code

N91, N92,

ICD-10 code description

Absent, scanty and rare menstruation, Excessive, frequent and irregular menstruation, Other abnormal uterine and vaginal bleeding

Primary outcomes

1

Description

amount of bleeding during operative hysteroscopy

Timepoint

one and two month after administration of Danazol and Diphereline respectively

Method of measurement

visual scale (0-5)

Secondary outcomes

1

Description

duration of hysteroscopy

Timepoint

one and two month after administration of Danazol and Diphereline respectively

Method of measurement

minutes measured by chronometer

2

Description

post operative bleeding

Timepoint

in 24 hour after hysteroscopy

Method of measurement

visual scale (0-5)

Intervention groups

1

Description

In second group intramuscular injection of diphereline 3.75 mg S.R are used before hysteroscopy, starting on day 18 of menstruation every 28 days for 2 month.

Category

Treatment - Drugs

2

Description

In first group 400 mg Danazol capsules are used every 12 hours placed into the posterior vaginal fornix for 30 days, starting on day 5 of menstruation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Prof. Dr. Manizheh Sayyahmelli

Street address

Southern Artesh Avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, Vice chancellor for Research

Full name of responsible person

Dr. Sanam Bidadi

Street address

Third floor, Central Building of Number 2, Gholghasht Avenue

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences, Vice chancellor for Research

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

Alzahra University Hospital

Full name of responsible person

Dr. Sanam Bidadi

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Southern Artesh Avenue, Baghshomal square

City

Tabriz

Postal code

5138665793

Phone

+98 41 1330 5749

Fax

+98 41 1334 1244

Email

sbidadi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alzahra University Hospital

Full name of responsible person

Manizheh Sayyahmelli

Position

Specialist of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Alzahra University Hospital, Baghshomal square, Southern Artesh Avenue, Tabriz

City

Tabriz

Postal code

5138665793

Phone

+98 411553916063

Fax

+98 41 1556 6449

Email

manizheh.sayyahmelli@gmail.com

sayyahmellim@tbzmed.ac.ir sbidadi@yahoo.com

Web page address

alzahrahosp.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Alzahra University Hospital, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Sanam Bidadi

Position

Resident of Obstetrics and gynecology

Other areas of specialty/work

Street address

Alzahra University Hospital, Baghshomal square, Southern Artesh Avenue, Tabriz

City

Tabriz

Postal code

5138665793

Phone

+98 41 1330 5749

Fax

+98 41 1334 1244

Email

sbidadi@yahoo.com

Web page address<http://alzahrahosp.tbzmed.ac.ir/>**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*