Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vaginal Danazol versus gonadtropin-releazing 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 gonadtropin-releazing hormone agonists will be compared in the management of intractable uterine hemorrhage during and post operative hystroscopy. 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

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Name of organization / entity

Tabriz University of Medical Sciences

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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 gonadtropin-releazing 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 genial tract infections; Patients using Anti coagulant drugs; Patients with sever 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 5/4/11092 و کد اخلاقی 91205

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 Danasol 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 Danasol 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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