Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of vitamin A on the Gestational Trophoblastic Neoplasia low risk pregnancy

Protocol summary

Summary

The purpose of this study was to determine the effect of combination therapy of Methotrexate with Vitamin A , in patients with low risk GTN (Gestational Trophoblastic Neoplasia. Intervention group, 19 patients with low-risk gestational trophoblastic neoplasia pulse weekly intramuscular methotrexate weekly associated with intravenous dose of 200,000 IU of vitamin A for 8 were. The control group received weekly intramuscular methotrexate weekly pulses. Serum levels of the hormone human chorionic gonadotropin beta (less than 5 international units per liter) in both groups will be reviewed on a weekly basis. Chemotherapy treatment and side effects of the two groups are compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120615676N1**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Sedigheh Ghasemian Dizaj Mehr

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

Email address

ghasemians901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-10-09, 1392/07/17

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin A on the Gestational Trophoblastic Neoplasia low risk pregnancy

Public title

Effect of combination therapy of Methotrexate with Vitamin A , in patients with low risk GTN (Gestational Trophoblastic Neoplasia)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: low risk Gestational Trophoblastic Neoplasia. Exclusion criteria: pregnancy, side effects including methotrexate and vitamin A, medical diseases (diseases of the cerebral, eye, cutaneous, liver).

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **49**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad, Khorasan Razavi, Iran
City
Mashhad
Postal code
Approval date
2013-10-09, 1392/07/17
Ethics committee reference number
920326

Health conditions studied

1

Description of health condition studied
Gestational Trophoblastic Neoplasia
ICD-10 code
D09.7
ICD-10 code description
Carcinoma in situ of other specified sites

Primary outcomes

1

Description
Beta HCG
Timepoint
Weekly
Method of measurement
mIU/ml

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: pulse weekly intramuscular methotrexate weekly associated with intramuscular dose of 200,000 IU of vitamin A for 8
Category
Treatment - Drugs

2

Description
pulse weekly intramuscular methotrexate
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Quaem Research and Mdical Institute
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad, Khorasan Razavi, Iran
City
Mashhad
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, Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh ghasemian Dizaj Mehr
Position
Postgraduate Student of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad, Khorasan Razavi, Iran
City
Mashhad
Postal code
Phone
+98 51 3711 2488
Fax
Email
ghasemians901@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zohreh Yousefi
Position
Professor of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad, Khorasan Razavi, Iran
City
Mashhad
Postal code
Phone
+98 51318411538
Fax
Email
yousefiz@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Gasemian Dizaj Mehr
Position
Postgraduate Student of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Mashhad School of Medicine, Pardis University, Azadi Square, Mashhad, Khorasan Razavi, Iran
City
Mashhad
Postal code
Phone
+98 51 3711 2488
Fax
Email
Web page address

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