

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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

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Zohreh Yousefi

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Professor of Obstetrics and Gynecology

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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