

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Effervescent magnesium tab on the outcome of pregnancy in women who have hypomagnesemia

Protocol summary

Summary

This study is a randomized clinical trial that will evaluate the effect of magnesium tab on pregnancy. Participants will be selected from the population that will be referred to Beheshti and Alzahra Hospital Clinic. Individuals who will fulfill the inclusion criteria will be invited to participate in this study. Maternal serum magnesium levels of pregnant women with gestational age 12_14 weeks will be measured and those whose serum magnesium levels will be less than 1.9 mg per deciliter, will be selected. The participants will be randomly allocated to one of the two groups using a computer-generated table. Participants in group A, will be received 200mg effervescent magnesium tab from vittafit company once daily for one month, also they will consume one multimineral tab from alhavi company, that contains 100mg magnesium, once a day till the end of pregnancy. Participants in group B will be received one multimineral tab daily till the end of pregnancy. Participants with magnesium serum levels more than 1.9mg per deciliter will be considered as control group C randomly. They will just consume one multimineral tab once a day till the end of pregnancy. This study will evaluate the outcomes of pregnancy like Intra Uterine Growth Retardation, Preterm labor, Preterm Rapture of membranes, maternal BMI, Neonatal weight, pregnancy induced hypertension, Gestational Diabetes, Cramps of leg, Apgar Score between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121925611N1**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Elaheh Zarean

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3673 5044

Email address

zarean@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Effervescent magnesium tab on the outcome of pregnancy in women who have hypomagnesemia

Public title

The effect of Effervescent Magnesium tab in the hypomagnesemic pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.have tendency to involve in this study and sign the agreement 2.single pregnancy 3.gestational age 12-14wks 4.no acute renal disease 5.hypomagnesemia in interventional group and normal magnesium 6.no history chronic HTN 7.no history of overt diabetes 8.no history of severe anemia 9.no history of diagnostic heart disease. 10.no anomaly inthis pregnancy and previous ones. 11.no use of cigrrate and alcohol. 12.no molar pregnancy 13.no acute pancreatitis
Exclusion criteria: 1.discard the study. 2.inappropriate use of magnesium. 3.don't. Come for follow up. 4.interactable vomiting

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Isfahan University of Medical Science

Street address

Hezarjerib Ave.-Isfahan University of Medical Science

City

Isfahan

Postal code

81746-73461

Approval date

2014-09-24, 1393/07/02

Ethics committee reference number

393558

Health conditions studied

1

Description of health condition studied

Evaluation of outcomes of pregnancy in Effervescent magnesium tab consumers

ICD-10 code

O20,O29

ICD-10 code description

other maternal disorder predominantly related to pregnancy

Primary outcomes

1

Description

Intrauterine growth retardation

Timepoint

at delivery

Method of measurement

weight under10 percentile

2

Description

weight of neonate

Timepoint

at delivery

Method of measurement

kilogram

3

Description

preterm labor

Timepoint

at delivery

Method of measurement

labor before 37 weeks

4

Description

pregnancy induced hypertension

Timepoint

HTN after 20th weeks gestational age with or without proteinuria

Method of measurement

mm Hg with manometer

5

Description

Gestational Diabetes

Timepoint

26 to28

Method of measurement

oral gelocose challenge test (mg/dl)

6

Description

leg cramp

Timepoint

during pregnancy

Method of measurement

question

7

Description

Intra uterine fetal death

Timepoint

at delivery

Method of measurement

No fetal heart rate on sonography

8

Description

Apgar on 5 min

Timepoint

at delivery

Method of measurement

measure by Apgar scale

9

Description

Gestational age at delivery

Timepoint

at delivery

Method of measurement

gestational age

10

Description

times of admission at hospital

Timepoint

at delivery

Method of measurement

question

11

Description

maternal age at delivery

Timepoint

at delivery

Method of measurement

question

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: 200mg effervescent magnesium tab once a day until 1 month +multi mineral tab of Alhavi company contains 100mg magnesium,1tab daily till the end of pregnancy

Category

Treatment - Drugs

2

Description

Intervention group B: multimineral tab of alhavi company contains 100mg magnesium,1tab daily till delivery

Category

Treatment - Drugs

3

Description

Control group c: multimineral tab of alhavi company contains 100mg magnesium,1tab daily till delivery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital clinic

Full name of responsible person

Dr. Amal Tarjan

Street address

Motahari Ave. Shahid Beheshti Hospital

City

Isfahan

2

Recruitment center

Name of recruitment center

Alzahra Hospital cilinic

Full name of responsible person

Dr. Amal Tarjan

Street address

Sofeh Ave.Alzahra Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Mr.s Toghiani

Street address

Hezarjarib Ave.Isfahan University of Medical Science ,research unit

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Science

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**

Isfahan University of Medical Science

Full name of responsible person

Dr.Amal Tarjan

Position

Ob&Gyn resident

Other areas of specialty/work**Street address**

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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Science

Full name of responsible person

Dr. elahesh zarean

Position

perinatologist

Other areas of specialty/work**Street address**

Alzahra Hospital_obstetric and gynecologic unit

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Isfahan University of Medical Science

Full name of responsible person

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Position

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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