Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 wil 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 gastational age 12_14 weeks will be measured and those whose serum magnesium levels will be less than1.9 mg per deciliter,will be selected.The participants will be randomly allocated to one of the two groups using a camputer-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
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Iran (Islamic Republic of)
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+98 31 3673 5044
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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 Toghyani
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
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second Apadana Ave.after norozi str.Mahtab b.no.5
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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perinatalogist
Other areas of specialty/work
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Person responsible for updating data

Contact
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second Apadana Ave.after norozi str._Mahtab B._no.5
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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