Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vitamin C supplementation in the last month of pregnancy on neonatal bilirubin level

Protocol summary

Study aim

The effect of vitamin C supplementation in the last month of pregnancy on neonatal bilirubin level

Design

This study was a clinical trial and included two intervention and control groups that were randomly assigned to four blocks. This study is a three-blind type. Based on previous studies, the reported standard deviation for bilirubin was 3.5 to 4.5. Therefore, in this study, taking into account the probability of the first type error of 5% and the second type error of 20%, the mean difference between the two groups was equal to 2 mg / dl and the standard deviation of 4 mg / dl, the sample size was 64 in each group It was found that by assuming a 10% drop, 72 people in each group were considered.

Settings and conduct

144 healthy pregnant women who are 34 weeks pregnant will be randomly selected from among referrers to Qom health centers and divided into two groups of 72 intervention and control groups. Pregnancy is commonly administered to both groups in the same way, and the multi-vitamin mineral and iron supplementation is prescribed for both groups similar to other pregnant women and according to the instructions of the health center, but the intervention group from the beginning of the 35th week to the end A pregnant woman will receive a 500 mg vitamin C tablet that is manufactured by Oswah and will give the control group a placebo. Since prenatal care is normally done at weeks 36 and 37 to 39, each pill needs to be delivered to the attendant at each visit, and to ensure that the pills are present in the referral. The next packets will be empty. If the baby is born earlier than the 37th week (preterm), the study will be discontinued. Neither we (the researcher nor the statistician) nor the participants will know about which of the people, supplements or placebo are used (a triple blind study). At the end of the infant, the infants will be under the supervision of a neonatal specialist and based on the coordination of the blood sample taken from the heel of the infants on the fifth day (jaundice, caused by physiological failure in term neonates) routinely screened for All infants will be taken to determine the level of bilirubin.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age range 20 to 40 years ؛ Being on the 34th week of pregnancy ؛ Single pregnancy ؛ Willingness to participate in research and signing consent. Non-entry criteria: pregnancy-related illnesses such as gestational diabetes, gestational hypertension, or hypothyroidism in pregnancy ؛ Having severe anemia ؛ Hepatic Diseases ؛ Renal diseases ؛ birth history of premature and low birth weight ؛ Family history of favism ؛ lactation at the same time as pregnancy ؛ use of aspirin and anticoagulants ؛ smoking.

Intervention groups

We will have two intervention groups. A group of 72 people who will receive a supplement of 500 milligrams of vitamin C from the beginning of the 35th week until the end of pregnancy, and 72 patients in the placebo group will recieve a 500 mg starch tablet from the beginning of the 35th week to the end of pregnancy.

Main outcome variables

Neonatal blood bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N47**
Registration date: **2018-03-11, 1396/12/20**
Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**
Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name
Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8862 2755
Email address
shidfar.f@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-22, 1397/03/01
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin C supplementation in the last month of pregnancy on neonatal bilirubin level

Public title
The effect of vitamin C supplementation in the last month of pregnancy on neonatal bilirubin level
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being on the 34th week of pregnancy Single pregnancy Willingness to participate in research and signing consent Age range 20 to 40 years
Exclusion criteria:
pregnancy-related illnesses such as gestational diabetes, gestational hypertension, or hypothyroidism in pregnancy Having severe anemia Hepatic Diseases Renal diseases birth history of premature and low birth weight Family history of favism lactation at the same time as pregnancy use of aspirin and anticoagulants smoking
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, the permuted block randomization method will be used with quadruple blocks. Based on the sample size of 144, 36 blocks will be produced using the online site www.sealedenvelope.com. In order to apply the concealment in the randomization process, unique code will be used on the drug boxes, the code being generated by the software. By entering each individual into a study based on the generated sequence, the pack of the drug in which the code is registered will be assigned to the individual.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Neither our (researcher nor statistician) nor the participants will know which complement or placebo are used (a triple blind study)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Hemmat Highway, next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-01-30, 1396/11/10
Ethics committee reference number
IR.IUMS.REC 1396.9511323004

Health conditions studied

1

Description of health condition studied
Jaundice of infants
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Neonatal blood bilirubin level
Timepoint
Fifth day after birth
Method of measurement
A blood sample of the heel is used to determine the level of bilirubin. This test will be based on light irradiation and turbodometry.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use 500 mg Vitamin C supplement /manufactured by Oswah Pharmaceutical Company / Daily / From the beginning of the 35th week to the end of pregnancy.
Category
Prevention

2

Description
Control group: Use of placebo made from starch / manufactured by Oswah Pharmaceutical Company / Daily / From the beginning of the 35th week to the end of pregnancy
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Izadi Qom Hospital
Full name of responsible person
Dr. Nayereh Rahmati
Street address
Dez Azar Street - next to Izadi Hospital
City
Qom
Province
Ghoum
Postal code
88566-37158
Phone
+98 25 3721 1301
Email
hkia@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malakooti
Street address
Iran university of medical science, Hemmat expressway-
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
shidfar.f@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Health, Iran University of Medical Sciences, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code

۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Health, Iran University of Medical Sciences, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mojtaba Khadem Al-Hosseini Ardakani
Position
MS.c student in Health Sciences in Nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Iran University of medical science, Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 25 3774 8266
Email
m.khadem.nut@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, after being unidentified, there is no limit to the disclosure of information
When the data will become available and for how long
6 months after the end of the study
To whom data/document is available
There is no limit
Under which criteria data/document could be used
In order to develop relevant studies Keep your trust and mention the source
From where data/document is obtainable
m.khadem.nut@gmail.com
What processes are involved for a request to access data/document
Upon receipt of requests and reviews, documentats will be provided within a maximum of one month.
Comments