

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of chicory extract consumption by mothers on frequency of icter and neonatals, bilirubin in referrals to birth preparation classes of Sirjan , 2018

Protocol summary

Study aim

Determine the effect of chicory extract consumption by mothers on frequency of icter and neonatals, bilirubin in referrals to birth preparation classes of Sirjan , 2018

Design

Clinical randomised trial with two arm parallel group

Settings and conduct

The research population includes pregnant women referring to birth Preparation Classes and their newborns . The sampling method will be convenience. To assign the samples and to prevent the samples from contacting each other, they are taken from a center of intervention group samples and taken from another center of the control group. The sample size was estimated based on the statistical formula of 100 people in each group. In the intervention group, it is recommended that mothers take chicory sweats from the 36th week of gestation, 70 cc three times a day and continue this process during the first 2 weeks of lactation. In the first two weeks of birth, the neonates are followed up and the frequency of the physiologic and pathologic icter and the mean serum bilirubin (24 hours after birth and 3 days after birth) are measured and recorded using a BILI-CHECK device.

Participants/Inclusion and exclusion criteria

The gestational age is more than 36 weeks, Iranian nationality and willing to participate in the study are inclusion criteria. History of using chemical or herbal medicines, history of abortion, heart disease, thyroid diseases, gestational diabetes, and regular consumption of chicory are exclusion criteria.

Intervention groups

In the intervention group, it is recommended that mothers take chicory extract from the 36th week of gestation, 70 cc three times per day , and continue this process during the first 2 weeks of lactation. There is no intervention in the control group.

Main outcome variables

Frequency of icter Mean serum bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N6**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

Registration date

2018-08-19, 1397/05/28

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of chicory extract consumption by mothers on frequency of icter and neonatals, bilirubin in referrals to birth preparation classes of Sirjan , 2018

Public title
Effect of chicory on icter in neonatals

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age>36 week Consent for participation Iranian nationality Decide to deliveryin Sirjan positive blood group
Exclusion criteria:
Taking chemical drugs Taking herbal medicine Gestational diabetes, heart or thyroid disorders Taking chicory regularly history of abortion history of sensitivity to herbal medicine

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Not 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
Ethics committee of Rafsanjan University of Medical Sciences
Street address
Imam Ali Blvd
City
Rafsanjan
Province

Kerman
Postal code
7717933777
Approval date
2018-06-13, 1397/03/23
Ethics committee reference number
IR.RUMS.REC.1397.059

Health conditions studied

1

Description of health condition studied

Icter

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

Frequency of Icter

Timepoint

First two weeks of birth

Method of measurement

Checklist for record of Icter

2

Description

Mean of serum bilirubin

Timepoint

First day and three day post birth

Method of measurement

Bilicheck device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the 36th week of gestation, it consumes three times a day, 70 cc Chicory each times, made by Sha'af Shiraz, and continues the process until the first two weeks of lactation.

Category

Prevention

2

Description

Control group: There is no intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Gharazi Hospital

Full name of responsible person

Leila Badieneshin

Street address

Shafa Ave., Malekashtar Blvd

City

Sirjan

Province

Kerman

Postal code

7817835816

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+98 34 4142 2200

Email

leila.badiye95@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable