

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The study of effect of motivational interviewing on adherence to iron supplementation and prenatal diagnostic test in couples suspected to have β - thalassemia, referring to premarital counseling center, Zahedan

Protocol summary

Summary

The aim is to determine the effectiveness of motivational interviewing on the adherence to iron supplementation and prenatal diagnostic test in couples suspected to have β - thalassemia, referring to premarital counseling center, Zahedan in 1394. This study is a single-blind randomized clinical trial. The population of the study are all couples who are referred to Premarital counseling center in Zahedan in 1394 . The sample size is 70 Couples. They will be allocated in intervention or control groups, randomly. Half of the couples will be held in the intervention group and half in the control group. "Block Randomization" will be used to allocate couples in the groups. Sampling will be done during four months. The main criteria for inclusion are: lack of psychological illness; participate in counseling sessions other than advice provided by the Thalassemia Advisory Centre. And exclusion criteria are: pregnant women, women with age over 45 years, illiteracy, not participation in all counseling sessions. Three counselling session (motivational interview) that each one will last about 90-minute will be held for each couples. One months later, the number, type and dose of iron tablets that are intake by couples, As well, the MCV, MCH, and HbA2 Will be considered. And each couple for doing prenatal diagnostic tests will be followed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061022651N1**

Registration date: **2015-08-01, 1394/05/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

Name

Zahra Moudi

Name of organization / entity

Zahedan University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zahedan University Of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of effect of motivational interviewing on adherence to iron supplementation and prenatal diagnostic test in couples suspected to have β - thalassemia, referring to premarital counseling center, Zahedan

Public title

The study of effect of motivational interviewing on

adherence to iron supplementation and prenatal diagnostic test in couples suspected to have β -thalassemia, referring to pamarital counseling center, Zahedan

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: lack of psychological illness; participate in counseling sessions other than advice provided by the Thalassemia Advisory Centre. Exclusion criteria:: pregnant women, women with age over 45 years, illiteracy, not participation in all counseling sessions.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

zahedan university of Medical Sciences

Street address

field doctor hesabi - College of Medical Sciences

City

zahedan

Postal code

9816743463

Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

IR.ZAUMS.REC.1394.102

Health conditions studied

1

Description of health condition studied

Haemolytic anaemias

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

The first stage of prenatal diagnosis test

Timepoint

Two months after the intervention

Method of measurement

Couples cases

Secondary outcomes

1

Description

Measurement Of MCV

Timepoint

Before and one month after intervention

Method of measurement

Check tests

2

Description

Adherence to iron supplementation

Timepoint

One month after the intervention

Method of measurement

Asked about the number of iron consumption

3

Description

Measurement Of MCH

Timepoint

Before and one month after

Method of measurement

Check tests

4

Description

Measurement of HbA2

Timepoint

Before and one month after

Method of measurement

Check tests

Intervention groups

1

Description

Control group received only routine counseling in Premarital counseling center.

Category

Other

2**Description**

Apart from routine advice in Premarital counseling center, three 90-minute sessions of individual counseling, motivational interviewing intervention group held.

Category

Other

Recruitment centers1**Recruitment center****Name of recruitment center**

Premarital Counseling Center

Full name of responsible person

Mansore Havashenas

Street address

Premarital Counseling Center, Crossroads Modarres

City

Zahedan

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Research Assistant Zahedan University of Medical Sciences

Full name of responsible person

Hoshang Rafighdost

Street address

Field doctor Hesabi, Zahedan University of Medical Sciences

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Assistant Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Esmat Dehghani

Position

Masters student in the field Consultation of midwifery

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

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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