

# 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 $\beta$ - 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  $\beta$ - 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)

###### Phone

+98 915 341 1005

###### Email address

moudi@zaums.ac.ir

##### 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  $\beta$ - 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  $\beta$ -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**

۹۸۱۶۷۴۳۴۶۳

#### **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 centers**1**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 sources**1**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**

School of Nursing and Midwifery, Square Of Mashahir, Zahedan

**City**

Zahedan

**Postal code**

9816913396

**Phone**

+98 33442482

**Fax**

+98 54 3344 2481

**Email**

Dehghani\_1361@yahoo.com

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

Zahedan University of Medical Sciences

**Full name of responsible person**

Zahra Moudi

**Position**

PhD in Reproductive Health

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

School of Nursing and Midwifery, Square Of Mashahir, Zahedan

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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*