

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of treatment with nicotine patches versus support behavior in smoking cessation in pregnant women

Protocol summary

Study aim

abstinence from the date of smoking cessation until delivery

Design

Two arm parallel group randomized trial, double - blind , placebo- controlled to assess nicotine - replacement patches for prolonged abstinence from smoking during pregnancy

Settings and conduct

Midwives researches study enrollment of women who agreed with the quit in two weeks. Subjects randomly received 4 weeks of patches of skin (containing 15 mg of nicotine every 16 hours) in place of placebo for delivery to mothers and one month after the start of the study, salivary cotinin test was taken from mothers who said they did not smoke. When less than 8 ppm, nicotine patches were given to moms for another 4 weeks. The patches of the placebo group are very similar to nicotine patches.

Participants/Inclusion and exclusion criteria

inclusion criteria : women who agreed to set a quit date , 16 to 50 years of age , 12 to 24 weeks of gestation , smoked 10 or more cigarettes daily before pregnancy, currently smoked 5 or more cigarettes daily exclusion criteria : known major fetal abnormalities , inability to provide informed consent , chemical or alcohol dependence , chronic generalized skin disorders

Intervention groups

pregnancies of 12 -24 to weeks gestation

Main outcome variables

abstinence from the date of smoking cessation until delivery - out comes for the fetus and baby: miscarriage , stillbirth , neonatal death , congenital abnormality , neonatal convulsion , birth weight

General information

Reason for update

Acronym

NRT

IRCT registration information

IRCT registration number: **IRCT20181209041904N1**
Registration date: **2018-12-21, 1397/09/30**
Registration timing: **prospective**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

zohre gozidehkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3258 3449

Email address

zohre.gozidehkar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-26, 1398/01/06

Expected recruitment end date

2022-03-26, 1401/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of treatment with nicotine patches versus support behavior in smoking cessation in pregnant women

Public title

Nicotine-Replacement Therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 16-50 years 12-24 weeks of pregnancy Smoking is 10 or more cigarettes a day before pregnancy Daily smoking of 5 yarns during the current pregnancy

Exclusion criteria:

Maternal mothers who have been diagnosed with ultrasound diagnosis of fetal abnormalities. Pregnant women who are allergic to chemicals or alcohol Pregnant mothers with generalized skin diseases Pregnancy mothers who are allergic to nicotine patches

Age

From **16 years** old to **50 years** old

Gender

Female

Phase

0

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **1050**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Individual randomization unit

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and midwives have been blinded to study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethnics committee of zahedan university of medical sciences

Street address

dr hesabi aveniu

City

zhedan

Province

Sistan-va-Balouchestan

Postal code

9769144155

Approval date

2018-11-12, 1397/08/21

Ethics committee reference number

354554

Health conditions studied**1****Description of health condition studied**

Addiction in pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

self-reported abstinence from smoking between the quit date and child-birth

Timepoint

Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention, the delivery time

Method of measurement

Perform salivary catechin test and CO respiration test

Secondary outcomes**1****Description**

Consequences of birth include: abortion - stillbirth - birth weight - congenital anomaly

Timepoint

Delivery time

Method of measurement

Self-report pregnant mothers and perform salivary cotinine test

Intervention groups**1****Description**

Intervention group: Pregnant women 12-24 weeks of pregnancy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nashat Addiction Treatment Center

Full name of responsible person

zohre gozidehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number
256542

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

80

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
Zahedan University of Medical Sciences
Full name of responsible person
zohre gozidehkar
Position
student
Latest degree

Bachelor
Other areas of specialty/work
Epidemiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is unobtrusive when unrecognizable

When the data will become available and for how long

Start one-year access period after printing results

To whom data/document is available

Researcher of medical universities of Iran

Under which criteria data/document could be used

Use of methodology and study results is free

From where data/document is obtainable

Requests for documentation via e-mail

What processes are involved for a request to access data/document

After receiving the email, the response will be given one month later

Comments