Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of halogen light and vibroacoustic stimulation on nonreactive fetal heart rate pattern

Protocol summary

Summary

Background: One of the first-line assessment tool for fetal surveillance is the non stress test (NST). Although it is limited by a high rate of false-positive results, external stimulation from vibroacoustic and halogen light has been described to aid in provoking fetal response and promoting test results. Methods: 100 pregnant women with non reactive NST in 20 minutes were allocated in vibroacoustic stimulation group (N= 50) who received vibration from a standard fetal vibratory stimulator, and halogen light stimulation group (N= 50) who received from a halogen light source. Stimulators were applied to the lower abdomen above fetal head for a 3 and 10 seconds, respectively. Results were compared together and then to BPP scores as a backup test. We used Mann-Whitney U Test, chi-square Test, Fisher's Exact Test to compare variables in two groups.

General information

Acronym

NST (nonstress test)

IRCT registration information

IRCT registration number: **IRCT201011275261N1**

Registration date: **2011-09-03, 1390/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-03, 1390/06/12

Registrant information

Name

Tahereh Rahiminia

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 4490 4272

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran university of medical sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of halogen light and vibroacoustic stimulation on nonreactive fetal heart rate pattern

Public title

Halogen light stimulation in fetal well being assessment

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: talking and undrestanding in Farsi; gestational age of 32-42; single and cephalic pregnancy; absence of known fetal abnormalities; no labour pain and vaginal bleeding. Exclusion criteria: any deceleration during nonstress testing.

Age

No age limit

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
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
Vice chancellor for research of Tehran University of Medical Sciences
Street address
Keshavarz Blvd, Qhods St
City
Tehran
Postal code
1417653761
Approval date
2011-07-28, 1390/05/06
Ethics committee reference number
130/657/90/د

Health conditions studied

1

Description of health condition studied
fetal well being assessment
ICD-10 code
P00
ICD-10 code description
Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy

2

Description of health condition studied
fetal well being assessment
ICD-10 code
P96
ICD-10 code description
Other conditions originating in the perinatal period

3

Description of health condition studied
fetal well being assessment
ICD-10 code
P01
ICD-10 code description
Fetus and newborn affected by maternal complications of pregnancy

4

Description of health condition studied
fetal well being assessment
ICD-10 code
P02
ICD-10 code description
Fetus and newborn affected by complications of placenta, cord and membranes

5

Description of health condition studied
fetal well being assessment
ICD-10 code
P02
ICD-10 code description
Fetus and newborn affected by complications of placenta, cord and membranes

Primary outcomes

1

Description
nonstress test results
Timepoint
the duration of testing time in reactive result , and in nonreactive pattern , the time is up to 20 minutes
Method of measurement
fetal heart rate record tracing in beats /minutes

2

Description
time to acceleration
Timepoint
the time elapsed to begining of fetal heart rate reactivity
Method of measurement
fetal heart rate record tracing, beats/minutes

3

Description
time to reactive pattern
Timepoint
the time elapsed to achive a reactive pattern (minutes)
Method of measurement
fetal heart rate record tracing, beats/minutes

Secondary outcomes

1

Description
biophysical profile
Timepoint
after stimulated testing, regardless of esults, biophysical profile scoring was done for all ones up to 30 minutes.
Method of measurement
sonography evaluation of four health qualities each one score of 2 and whole 8 in normal status.

Intervention groups

1

Description
In halogen light stimulation, the halogen light source)CE Spotlight, YUYAO SHUNYE ELECTRICAL APPLIANCES CO.,LTD, China) luminance of 1000,000 candle power. The 10-cm diameter light surface was placed gently to create a seal with the maternal abdominal midline just above the symphysis for 10 seconds. If an adequate FHR acceleration (15 beats/min above baseline for15 seconds) was absent after the 10-second light stimulation, then the stimulus was repeated at 10-minut intervals for a maximum of 3 times during the 20-minute NST.
Category
Diagnosis

2

Description
In vibroacoustic stimulation group an standard fetal stimulatory (FS-1 Fetal Stimulator, Edan Instruments, Inc. China) frequency of 80 Hertz for 3 seconds, above the symphysis was applied.If an adequate FHR acceleration (15 beats/min above baseline for15 seconds) was absent after the 10-second light stimulation, then the stimulus was repeated at 10-minut intervals for a maximum of 3 times during the 20-minute NST.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Mirza Kouchak khan hospital
Full name of responsible person
Tahereh Rahiminia
Street address
Nursing and Midwifery faculty, Tehran University of Medical Sciences, Tohid square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellory for research of Tehran University of Medical Sciences
Full name of responsible person
Neda Mehrdad PhD
Street address
Faculty of Nursing and Midwifery, Touhid Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellory for research of Tehran 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
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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