EFFECTIVENESS OF SUSTAINED NATURAL APOPHYSEAL GLIDES ON CERVICOGENIC HEADACHE IN FEMALE WITH CERVICOGENIC HEADACHE: A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim
The study was aimed to assess the effect of sustained natural apophyseal glides (SNAGs) in the treatment of cervicogenic headache.

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment.

Settings and conduct
The trial was completed at Safi Hospital Faisalabad. A sample of 40 female patients with cervicogenic headache aged 20 to 40 were randomly assigned into two groups, i.e. 20 subjects to treatment group and 20 subjects to control group. SNAGs were applied to treatment group while control group was treated with placebo treatment.

Participants/Inclusion and exclusion criteria
Inclusion Criteria • Females age group 20-40 years • Females with cervicogenic headache • Females with decreased range of motion of cervical region • Having at least one episode of CGH in previous 3 months
Exclusion Criteria • Females with migraine and tension type headache • Females with herniated disc, fracture, radiculopathy and trauma • Females with known congenital, inflammatory and infectious conditions of cervical spine

Intervention groups
This group was treated with SNAG to relieve neck pain and headache. The SNAGs were applied for 20 minutes in each session to the treatment group, alternative three days per week, a total of 12 times for four weeks.

Main outcome variables
The VAS (visual analogue scale) and the NDI (neck weakness index) were used as main outcome measures.

General information

Reason for update

Acronym
IRCT

IRCT registration information
IRCT registration number: IRCT20200221046567N3
Registration date: 2020-11-17, 1399/08/27
Registration timing: retrospective

Last update: 2020-11-17, 1399/08/27
Update count: 0

Registration date
2020-11-17, 1399/08/27

Registrant information
Name
Muhammad Kashif

Name of organization / entity
Riphah International University

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-01, 1397/12/10

Expected recruitment end date
2019-09-30, 1398/07/08

Actual recruitment start date
2019-03-01, 1397/12/10

Actual recruitment end date
2019-10-01, 1398/07/09

Trial completion date
2019-10-01, 1398/07/09

Scientific title
EFFECTIVENESS OF SUSTAINED NATURAL APOPHYSEAL GLIDES ON CERVICOGENIC HEADACHE IN FEMALE WITH CERVICOGENIC HEADACHE: A RANDOMIZED CONTROLLED TRIAL

Public title
EFFECTIVENESS OF SUSTAINED NATURAL APOPHYSEAL GLIDES ON CERVICOGENIC HEADACHE IN FEMALE WITH CERVICOGENIC HEADACHE

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Females age group 20-40 years with cervicogenic headache. Females with decreased range of motion of cervical region. Having at least one episode of CGH in previous 3 months

Exclusion criteria:
• Females with migraine and tension type headache
• Females with herniated disc, fracture, radiculopathy and trauma
• Females with known congenital, inflammatory and infectious conditions of cervical spine
• Females with neurogenic problem and surgical record

Age
From 20 years old to 40 years old

Gender
Female

Phase
N/A

Groups that have been masked
• Outcome assessor

Sample size
Target sample size: 40
Actual sample size reached: 40

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects were randomly assigned into two groups following simple randomization procedures (computerized random numbers)

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessors of the study was kept blind of the treatment group to which the patient will be allocated.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee

Research and Ethics Committee ,Riphah College of Rehabilitation Sciences, Pakistan.

Street address
Satiana Road

City
Faisalabad

Postal code
3800

Approval date
2019-02-15, 1397/11/26

Ethics committee reference number
RCRAHS/ERB/227

Health conditions studied

1
Description of health condition studied
CERVICOGENIC HEADACHE

ICD-10 code
G44.89

ICD-10 code description
CERVICOGENIC HEADACHE

Primary outcomes

1
Description
Pain

Timepoint
Baseline and 1, 2, 3 and end of intervention

Method of measurement
Visual Analogue Scale (VAS)

2
Description
Level of Neck Disability

Timepoint
Baseline and 1, 2, 3 and end of intervention

Method of measurement
Neck Disability Index (NDI)

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: The SNAGs were applied for 20 minutes in each session to the treatment group, alternative three days per week, a total of 12 times for four weeks.

Category
Treatment - Other
Control group: The control group received placebo treatment for 20 minutes, alternative three times per week, 2, a total of 12 times in four weeks.
Riphah International University

**Full name of responsible person**
Muhammad Kashif

**Position**
Associate professor

**Latest degree**
Master

**Other areas of specialty/work**
Physiotherapy

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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

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**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

**Title and more details about the data/document**
IPD collected for the primary outcome measure only

**When the data will become available and for how long**
starting 6 months after publication

**To whom data/document is available**
Academic institutions

**Under which criteria data/document could be used**
who want to compare/conduct studies on comparison of subtalar mobilization with conventional treatment for the management of CERVICOGENIC HEADCHE

**From where data/document is obtainable**
Principal Investigator by email: kashif.shaffi@gmail.com

**What processes are involved for a request to access data/document**
An email request to Principal Investigator email: kashif.shaffi@gmail.com

**Comments**