

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical Trial of Cranfixer

Protocol summary

Study aim

The main objective of this project is to evaluate the performance of the Cranfixer as claimed by the manufacturer

Design

This investigation was done in an Unblinded manner. The report was provided from the results obtained during surgery as well as post-operative follow-up.

Settings and conduct

This product has a license from the Iranian Medical Devices Directorate and the related risks are reviewed based on the essential requirements and estimated by the FMEA method, and the points are mentioned to adverse events in the instructions sheet. This study is carried out at the hospital site and also by conducting follow-up from the manufacturer's site.

Participants/Inclusion and exclusion criteria

The application of this product is in neurosurgery. The patients with craniotomy are potentially candidate to use this product. There is no limitation in terms of age and sex.

Intervention groups

The patients with craniotomy in neurosurgery

Main outcome variables

Loosening; Infection; Prominence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043740N1**

Registration date: **2019-06-07, 1398/03/17**

Registration timing: **retrospective**

Last update: **2019-06-07, 1398/03/17**

Update count: **0**

Registration date

2019-06-07, 1398/03/17

Registrant information

Name

Seyed Roholah Ghodsi

Name of organization / entity

Danawell

Country

Iran (Islamic Republic of)

Phone

+98 21 8338 4167

Email address

dr.sr.ghodsi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-15, 1396/11/26

Expected recruitment end date

2018-09-17, 1397/06/26

Actual recruitment start date

2018-02-15, 1396/11/26

Actual recruitment end date

2018-12-20, 1397/09/29

Trial completion date

2019-05-02, 1398/02/12

Scientific title

Clinical Trial of Cranfixer

Public title

Cranfixer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neurosurgery that leads to the separation of the skull's flap

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

In the most cases, two Cranfixer are used to fix the flap for each patient

Actual sample size reached: **66**

More than 1 sample in each individual

Actual sample size in each individual: **2**

In the most cases, two Cranfixer are used to fix the flap for each patient

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs - Tehran
University of Medical Sciences

Street address

Qods st., Tehran University of Medical Science (TUMS)

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-12-11, 1397/09/20

Ethics committee reference number

IR.TUMS.VCR.REC.1397.657

Health conditions studied

1

Description of health condition studied

Flap Fixation instrument (Burr Hole Cover)

ICD-10 code

T84.2

ICD-10 code description

Mechanical complication of internal fixation device of

other bones

Primary outcomes

1

Description

Skull Flap Loosening

Timepoint

At least 6 month after surgery

Method of measurement

Qualitative Study (Touch)

2

Description

Infection

Timepoint

2 to 4 weeks after surgery

Method of measurement

Infection detection

Secondary outcomes

1

Description

Non-Touchable from The skin

Timepoint

At least 6 month after surgery

Method of measurement

Qualitative Study (Touch)

Intervention groups

1

Description

Intervention group: Cranfixer

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahman Hospital

Full name of responsible person

Ramin Hasani

Street address

Shahrgharb,NourthIran zamin, Tehran

City

Tehran

Province

Tehran

Postal code

1465795481

Phone

+98 21 8857 5901

Email
raminhasaniiii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Darman Afarin Noandish Afagh

Full name of responsible person

Seyed Roholah Ghodsi

Street address

Dental Martial Incubation Center, Tehran University of
Medical Science

City

Tehran

Province

Tehran

Postal code

1417614361

Phone

+98 21 8338 4167

Fax

+98 21 8338 4169

Email

info@danawell.com

Web page address

http://www.danawell.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Darman Afarin Noandish Afagh

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Darman Afarin Noandish Afagh

Full name of responsible person

Seyed Roholah Ghodsi

Position

CEO

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

Street address

Qods st.

City

Tehran

Province

Tehran

Postal code

1417614361

Phone

+98 21 8338 4167

Fax

+98 21 8338 4169

Email

roholahghodsi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Ghodsi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

Street address

Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8338 4167

Email

ghodsism@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Darman Afarin Noandish Afagh

Full name of responsible person

Zahra Faraji

Position

Organization representative

Latest degree

Master

Other areas of specialty/work

Medical Engineering

Street address

Qods st.

City

Tehran

Province

Tehran

Postal code

1417614361

Phone

+98 21 8338 4167

Fax

+98 21 8338 4169

Email

zahrafaraji63@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Table of postoperative Information of patients. Data will be shared after unidentifiable people.

When the data will become available and for how long

Access to data is possible at the time of publishing results

To whom data/document is available

Individuals approved by the this team and the manufacturer

Under which criteria data/document could be used

If a person wants to access patient files, such as CT-scan for further study, it is possible with the manufacturer's permission. furthermore, the provided report from this study should be published with permission and the name of the manufacturer.

From where data/document is obtainable

Darman Afarin Noandish Afagh Company

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

After the Submission of request and the confirmation, the information is provided by the company representative.

Comments