

Optimalisation prone procedure and prone positioning in the operating room using the Inflatable Board and Inflatable Prone Support.

Published: 04-03-2019

Last updated: 10-01-2025

To obtain user and medical staff feed-back on the safety, clinical performance and ergonomic features of the IPS and IBO.

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON48353

Source

ToetsingOnline

Brief title

User test IPS-IBO

Condition

- Bone and joint therapeutic procedures

Synonym

prone, spine surgery

Research involving

Human

Sponsors and support

Primary sponsor: Ergotrics NV

Source(s) of monetary or material Support: Ergotrics

Intervention

Keyword: inflatable, prone positioning, proning procedure

Outcome measures

Primary outcome

Evaluation stability prone position (by surgeon)

Evaluation proning and positioning by anesthesiologist

Evaluation prone position by anesthesiologist

Evaluation ergonomic and hygienic features by medical staff

Evaluation of usability

Evaluation required number of staff members

Time required for proning / time in prone position

Peri-operative adverse events

Secondary outcome

none

Study description

Background summary

The prone position has been used in a wide variety of operations since the 1930s. Currently the proning and positioning of the patient requires physical power and puts an ergonomic burden on the medical staff. Ergotrics developed products which allow for the optimal moving and positioning of patients in prone position without the need for physical power. This is a user test.

Study objective

To obtain user and medical staff feed-back on the safety, clinical performance and ergonomic features of the IPS and IBO.

Study design

single arm, single center user test

Intervention

proning using the IBO (Inflatable BOard)
positioning using the IPS (Inflatable Prone Support)

Study burden and risks

none

Contacts

Public

Ergotrics NV

Bredaseweg 20
Hoogstraten 2322
BE

Scientific

Ergotrics NV

Bredaseweg 20
Hoogstraten 2322
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

From 18 years of age

Male

Scheduled to undergo non-instrumented lumbar spine surgery in prone position

Signed Informed Consent Form

Exclusion criteria

Known sensitivity to polyvinylchloride or polyamide

Overweight patient (> 150 kg)

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 24-04-2019

Enrollment: 5

Type: Actual

Medical products/devices used

Generic name: Inflatable BOard (IBO) en Inflatable Prone Support (IPS)

Registration: No

Ethics review

Approved WMO

Date:	04-03-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68064.028.18

Study results

Date completed:	02-08-2019
Results posted:	20-12-2018

First publication
20-12-2018