Study of the change in Intra-Abdominal Pressure during spine surgery in the prone position

Published: 27-05-2020
Last updated: 08-04-2024

To assess the change in Intra-Abdominal Pressure (IAP), measured via indwelling urinary catheter, when using the IPS for positioning a subject in prone position for spine surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON49958

Source
ToetsingOnline

Brief title
SIAP - Spine Intra-Abdominal Pressure study

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
intra-abdominal pressure, pressure within the abdominal cavity

Research involving
Human

Sponsors and support

Primary sponsor: Ergotrics nv
Source(s) of monetary or material Support: Ergotrics nv

Intervention

Keyword: Intra-Abdominal Pressure, Prone positioning

Outcome measures

Primary outcome

The change in Intra-Abdominal Pressure (IAP) caused by inflation of the IPS (IAP before inflation versus IAP after inflation of the IPS) with the subject under general anesthesia in prone position.

Secondary outcome

Change in IAP over time (supine before proning, prone before IPS inflation, prone after IPS inflation, prone 45 minutes after IPS inflation, at end of surgery and supine after regaining consciousness from anesthesia).

Impact of BMI on IAP change when using the IPS

Impact of body weight on IAP change when using the IPS

Impact of body morphology on IAP change when using the IPS

Impact of delta IAP (difference between the end-inspiratory and the end-expiratory IAP) at baseline on IAP change.

Blood loss and correlation with IAP

Serious adverse events at 48 hours post procedure

Study description

Background summary

The prone position has been used to provide posterior surgical access in a wide variety of operations since the 1930s. Whenever patient position is changed from supine to prone, the Intra-Abdominal Pressure (IAP) increases due to abdominal compression in the prone position. The rise in IAP can cause venous

congestion in the pelvis and abdomen. This may lead to backflow of venous blood into the large valveless vertebral venous system, which can result in venous congestion in the rigid spinal canal and increase bleeding which makes spinal surgery complicated.

Spine surgeons are concerned about intraoperative bleeding during spinal surgery because even minor bleeding can obstruct the surgeon*s field of vision resulting in difficulties in microsurgical manipulation. In addition, significant blood loss during spinal surgery is associated with unfavorable surgical outcomes and prolonged hospital stays.

Therefore patients in prone position are positioned in a manner to offload the abdomen (*free hanging*) as much as possible to avoid an increased IAP. Different positioning tools exist such as the Wilson frame, pads, bolsters and more recently the Inflatable Prone Support (IPS).

Study objective

To assess the change in Intra-Abdominal Pressure (IAP), measured via indwelling urinary catheter, when using the IPS for positioning a subject in prone position for spine surgery.

Study design

Prospective, observational, single-arm, monocenter study

Study burden and risks

No burden to the patient
The risks associated with the IPS are the same as those during use of the IPS outside the study.
The risks associated with the transurethral bladder catheter are the same as for subjects not participating in this study. Subjects undergoing a surgical procedure often receive a transurethral bladder catheter per standard of care. In this study only subjects with a transurethral bladder catheter in place are enrolled. Therefore the risks related to the transurethral bladder catheter are the same as for subjects not participating in this study.
The risk related to the IAP measurement is minimal. The external pressure transducer is connected to a port of the transurethral bladder catheter. There are no known risk related to the use of the external pressure transducer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-80 at time of surgery
Subject planned to undergo spine surgery in prone position
Subject planned to have transurethral bladder catheter during surgery
Body weight * 120kg

Exclusion criteria

Abdominal or urethral surgery during past 12 months.
Contraindication to use of transurethral bladder catheter
History of recent (<3 months) urinary tract or bladder infection.
Known allergy to IPS material
Current systemic infection or local infection
Current known pregnancy
Subject is participating in an investigational study

Coagulation Issues/disorders

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	20-10-2020
Application type:	Amendment
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	NL72983.028.20

Study results

Date completed:	30-03-2022
Actual enrolment:	40