The immunomodulatory effect of sugammadex after total hip replacement surgery under neuraxial anaesthesia: a pilot study

Published: 07-11-2022
Last updated: 30-11-2024

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

Summary

ID

NL-OMON51373

Source
ToetsingOnline

Brief title
MAGIC study

Condition

- Bone and joint therapeutic procedures

Synonym
hip arthrosis, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Innate immune system, Neuraxial anesthesia, Sugammadex, Total hip replacement

Outcome measures

Primary outcome

Postoperative innate immune function as reflected by

- Ex vivo cytokine (TNF-α, IL-6, IL-10, IL-1β) production capacity of

mononuclear cells upon whole blood lipopolysaccharide (LPS) stimulation.

Secondary outcome

- Innate immune function at the end of surgery and postoperative day 1 as

reflected by

- Circulating inflammatory cytokines (TNF-α, IL-6, IL-10)

- DAMP release (HSP70, HMGB1)

- Pain scores (NRS 0-10) and total analgesia consumption at the post anesthesia

care unit (PACU) and postoperative day 1.

- Quality of Recovery score (QoR-40) at postoperative day 1(11).

- Innate immune function prior to incision

- 30-day postoperative infectious complications scored according to the

relevant endpoint of the StEP-COMPAC group initiative

- 30-day postoperative complications scored by Clavien Dindo classification.

Study description

Background summary

Infections are the number one complication after surgery. Moreover it is known that surgery itself, combined with anaesthesia, has a negative impact on immunity through several mechanisms. Seen the potentially devestating result of postoperative infectious complications, more research is aimed at therapeutic strategies that positively influence the postoperative immune dysregulation.
Our group aimed at reducing surgical stress by use of a deep neuromuscular blockade. In this search we found evidence that sugammadex, used to antogonize neuromuscular blockade, may have an immunomodulatory effect itself. Ex vivo analysis showed that sugammadex counteracted the immunosuppressive effect of rocuronium, but even in absence of rocuronium it had a positive effect on cytokine production capacity (see pages 9-11 of the protocol for the exact data).
These results raise the question wether sugammadex truly has an immunomodulatory potention. Therefore, we now propose a pilot study to investigate this.

Study objective

The overall objective of this study is to investigate the potential immunomodulatory effect of sugammadex as seen in previous ex vivo experiments. Specified, the main objective is to investigate the effect of administration of sugammadex without prior neuromuscular blockade on postoperative innate immune function as reflected by cytokine production capacity of mononuclear cells.

Study design

A randomized blinded pilot study

Intervention

The experimental group will receive sugammadex (8mg/kg) at the end of surgery, the control group will receive placebo (NaCl 0.9%) at the same moment.

Study burden and risks

Sugammadex is a registered and a safe drug which will be used in a dosage within normal therapeutical range. A specific study design with only sugammadex administration without prior neuromuscular blockade is chosen to evaluate the effect of solely sugammadex. Sugammadex administration without prior neuromuscular blockade is not thought to add additional risk. Any possible risk factors or interactions as mentioned in the Summary of Product Characteristics are covered by exclusion criteria in order to fully eliminate risk of participation. The burden of participation for patients consist mainly of withdrawal of extra blood samples. Blood samples will be obtained prior to surgery, twice during surgery and one day postoperative. Blood samples will be

combined with routine lab assessment as much as possible.

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 of 18 years or older
- Scheduled for total hip replacement surgery under neuraxial surgery
- Scheduled for primary hip replacement surgery
- Informed consent obtained

Exclusion criteria

- Insufficient control of the Dutch language to read the patient information and to fill out de questionnaires
- Mentally incapcitated patients
- Known or suspected hypersensitivity to sugammadex
- Deficiency of vitamin K dependent clotting factors or coagulopathy
- Severe renal disease (creatinine clearance <30 ml/min), including patients on dialysis)
- Severe liver disease (Child-Pugh Classification C)
- Women who are or may be pregnant or currently breastfeeding
- Women of childbearing potential who don't use adequate method of contraception
- Severe vertebral column disorder
- Chronic use of psychotropic drugs
- Known hypertrophic obstructive cardiomyopathy, severe aortic valve stenosis or severe mitral valve stenosis
- Chronic use of NSAID's, steroids or immunosuppressive drugs

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-03-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Bridion
Generic name:	Sugammadex
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-11-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2022-003325-22-NL
CCMO	NL82808.091.22