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Effect of 3% gelatin solution on kidney function in patients after thyroid gland removal

Submission date
06/04/2021

Recruitment status
No longer recruiting

Registration date
08/04/2021

Overall study status
Completed

Last Edited
10/12/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In recent years much research has focused on the harmful effects of colloids used in patients hospitalized in the Intensive Care Unit (ICU). Only a few researchers have addressed the problem of the adverse effects of gelatin given during the surgical procedure. The optimal fluid therapy before surgery is intended to maintain a euvolemic state (the normal amount of body fluids) and replenish the possible fluid losses associated with surgery. It ensures the proper function of the circulatory system, optimal tissue perfusion and kidney function. Maintaining balanced fluid therapy is extremely difficult – the fluid type, volume, and rate of administration have to be adjusted to the type of surgery, its duration, preoperative fluid deficits, potential fluid losses, and the patients' other illnesses. The level of kidney injury molecule-1 (KIM-1) is low in healthy people and usually undetectable in the urine, but it increases markedly within hours following kidney injury. Therefore, the aim of this study is to investigate the effect of the gelatin solution used during a thyroidectomy (surgical removal of all or part of the thyroid gland) on kidney function using the urinary KIM-1 (uKIM-1) level.

Who can participate?
Patients aged 18-80 undergoing partial or total thyroidectomy

What does the study involve?
Participanys are randomly allocated to one of three groups. The patients from the first group A (experimental) receive 3% gelatin solution at a dose of 30 ml/kg body weight during the first hour of the procedure and then an isotonic multi-electrolyte solution at a dose of 15 ml/kg body weight/hour. The patients from the second group B (experimental) receive 3% gelatin solution at a dose of 15 ml/kg body weight during the first hour of the procedure and then the isotonic multi-electrolyte solution at a dose of 15 ml/kg body weight/hour. The patients from the third group C (control) receive an active-controlled intervention in the form of isotonic multi-electrolyte solution at a dose of 30 ml/kg body weight during the first hour of the procedure and then the isotonic multi-electrolyte at a dose of 15 ml/kg body weight/ hour. The following parameters are assessed: changes in the uKIM-1 level determined from urine samples; changes in the serum creatinine level determined from blood; and the level of selected vital signs.

What are the possible benefits and risks of participating?
The main general purpose of the study is prevention in terms of assuring proper kidney function and preventing kidney damage. All patients will be carefully monitored regarding possible adverse events such as allergic reaction to local anesthetics, technical difficulties of the blockade, or hematoma.

Where is the study run from?
1. 4th Military Hospital of Wroclaw (Poland)
2. Wroclaw Medical University (Poland)

When is the study starting and how long is it expected to run for?
April 2013 to December 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Patrycja Leśnik
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of the efficacy of 3% gelatin solution at a dose of 15 ml/kg versus a dose of 30 ml/kg body weight during the first hour of the thyroidectomy procedure on renal function based on urinary kidney injury molecule-1

Study objectives
This study proves that the urinary kidney injury molecule-1 (uKIM-1) level could be an early and sensitive biomarker of kidney injury. Renal toxicity of the gelatin solution evaluated based on the uKIM-1 level, correlates with the administered volume of fluid. Restrictive fluid therapy with the 3% gelatin solution seems to be safe in patients without underlying kidney injury undergoing surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2013, Bioethics Committee of the Wroclaw Medical University (Pasteura 1, 50-367 Wroclaw, Poland; +48 (0)71 784 10 14; bioetyka@umed.wroc.pl), ref: KB–283/2013

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Renal function after thyroidectomy

Interventions
The project is performed in the Department of Anesthesiology and Intensive Care of the University Hospital of Wroclaw in Poland. Adult patients of both sexes qualified for planned thyroidectomy procedures are included in the study.

Patients are randomly assigned to three comparison groups who receive a different dose of 3% gelatin solution during the thyroidectomy procedure.

The patients from the first group A (experimental) receive an anesthesiologic intervention in the form of 3% gelatin solution (Geloplasma, Fresenius Kabi, Poland) at a dose of 30 ml/kg body weight during the first hour of the procedure and then the isotonic multi-electrolyte solution (Isolyte®, Fresenius Kabi, Poland) at a dose of 15 ml/kg body weight/hour.

The patients from the second group B (experimental) receive an anesthesiologic intervention in the form of 3% gelatin solution (Geloplasma®, Fresenius Kabi, Poland) at a dose of 15 ml/kg body weight during the first hour of the procedure and then the isotonic multi-electrolyte solution (Isolyte®, Fresenius Kabi, Poland) at a dose of 15 ml/kg body weight/hour.

The patients from the third group C (control) receive an active-controlled intervention in the form of isotonic multi-electrolyte Solution (Isolyte®, Fresenius Kabi, Warsaw, Poland) at a dose of 30 ml/kg body weight during the first hour of the procedure and then the isotonic multi-electrolyte solution (Isolyte®, Fresenius Kabi, Warsaw, Poland) at a dose of 15 ml/kg body weight/ hour.

The person performing the above-mentioned experimental procedures is the same anesthesiologist with at least 5 years of professional expertise.

In order to monitor the intensity of pain and possible verifying the treatment, the patient's documentation are routinely recorded: haemodynamic stability of the patient during the procedure (heart rate, blood pressure - data were obtained from the anaesthesia protocol), the intensity of pain, the need for the supply of coanalgesics and the number of complications and side effects.

Clinical parameters such as heart rate (continuous measurement), arterial blood saturation (continuous measurement), systolic, and diastolic pressure (measurement every 5 minutes) are collected from the anaesthesia protocol.

The creatinine level is measured and urine samples are taken to determine the initial concentration of uKIM-1 during a routine examination before the surgery and then 2 and 24 hours after the surgery. Urine samples of 15 ml are collected in urinary cups and centrifuged at 2000-3000 rpm for 20 minutes, and the supernatant is kept at -72 °C. The quantitative determination of uKIM-1 is performed using an enzyme-linked immunoassay (ELISA) kit supplied by R&D Systems Inc. (Minneapolis, USA).

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. Changes in the urinary kidney injury molecule-1 (uKIM-1) level determined from urine samples using an enzyme-linked immunoassay (ELISA) method at baseline, postoperative 2 hours, and 24 hours
2. Changes in the serum creatinine level determined from venous blood samples using laboratory methods at baseline, postoperative 2 hours, and 24 hours

Key secondary outcome(s))
The level of selected vital signs (heart rate, blood pressure, SaO_2) in the clinical monitoring of hemodynamic stability and anaesthesia effectiveness at baseline, intraoperative every 15 minutes of the procedure, and postoperative 15 minutes, 30 minutes, 45 minutes, and 60 minutes

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Patients qualified for partial or total thyroidectomy
2. Age between 18-80 years old
3. ASA (American Society of Anesthesiologist Physical Status Classification System) score of I or II
4. The lack of contraindications for the administration of 3% gelatin solution (gelatin allergy)
5. The lack of blood coagulation disorders and the lack of allergy to anaesthetic agents
6. The obtained informed and written consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Age < 18 years old and > 80 years old
2. ASA (American Society of Anesthesiologist Physical Status Classification System) score of III or IV

3. Impaired renal function prior to the surgery (serum creatinine >1.3 mg/dl)
4. Undergoing immunosuppressive therapy
5. Contraindications for the administration of 3% gelatin solution (gelatin allergy)
6. Coagulation disorders as a contraindication for anaesthesia
7. Allergy to local anaesthetics
8. The lack of obtained informed and written consent to participate in the study

Date of first enrolment
01/02/2014

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
Poland

Study participating centre
4th Military Hospital of Wroclaw
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Sponsor information

Organisation
4th Military Hospital of Wroclaw

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Patrycja Leśnik (patrycja.lesnik@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/12/2021	10/12/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes