

Met-Hb and inflammation markers with tumescence local anaesthesia (TLA)

Submission date 12/12/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/03/2008	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 20/03/2008	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
anaesMA2007-02

Study information

Scientific Title
Met-Hb-concentration and inflammation markers in patients undergoing tumescence local anaesthesia (TLA) with supramaximal dosages of prilocaine

Study objectives

Tumescence local anaesthesia (TLA) is an established anaesthesia technique, where large amounts of highly diluted local anaesthetics are used. Due to its low toxicity, prilocaine is used frequently. Though, prilocaine can - dosage-dependant - cause a methemoglobinaemia, leading to a reduced oxygen transport capacity. Furthermore, certain processes of the inflammation cascade are initiated. These effects are important for ambulatory patients and the following healing process.

The aim of the study is to evaluate the Met-Hb concentration and inflammation markers like interleukin-1 (IL-1), interleukin-6 (IL-6) and interleukin-8 (IL-8), tumour necrotising factor (TNF), C-reactive protein (CRP) in a chronological sequence.

Hypothesis:

TLA in supramaximal dosages of prilocaine has an influence on plasmatic inflammation markers, which will elevate in the first 48 hours. Furthermore, the Met-Hb production will not be finished within this time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee (Medizinische Ethik-Kommission II: Medizinische Fakultät Mannheim der Ruprechts-Karls-Universität Heidelberg) on the 22nd November 2007 (ref: 2007-258N-MA)

Primary study design

Observational

Study design

Observational study until 48 hours after surgery

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Tumescence local anaesthesia (TLA)/established anaesthesia techniques

Interventions

As a standard procedure in our clinic, patients with dermatological operations will receive a TLA with more than 600 mg prilocaine. Seven blood samples (approximately 8 ml) will be taken 0, 1, 2, 4, 12, 24 and 48 hours after TLA, where the following parameters will be determined from:

1. Demographic data and vital parameters
2. Met-Hb-concentration
3. Prilocaine-concentration
4. IL-1
5. IL-6
6. IL-8
7. TNF-alpha
8. CRP
9. Procalcitonin (PCT)
10. Creatine kinase (CK)

11. Lactate dehydrogenase (LDH)
12. Reticulocytes
13. Myoglobin
14. Haptoglobin
15. Complications

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prilocaine

Primary outcome(s)

Met-Hb-concentration over the time, measured over 48 hours.

Key secondary outcome(s)

Elevation of inflammation markers, measured over 48 hours.

Completion date

01/07/2009

Eligibility

Key inclusion criteria

1. Patients (male/female) with operations which are performed in TLA with prilocaine
2. Age: 18 - 85 years
3. American Society of Anaesthesiologists (ASA) grade I - III
4. No allergy against prilocaine

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Allergy against prilocaine
2. Pregnancy
3. Patient denies operation in TLA

Date of first enrolment

01/02/2008

Date of final enrolment

01/07/2009

Locations

Countries of recruitment

Germany

Study participating centre

University Clinic Mannheim

Mannheim

Germany

68167

Sponsor information

Organisation

University Clinic Mannheim (Germany) - Department of Anaesthesiology and Critical Care Medicine

ROR

<https://ror.org/05sxbyd35>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Clinic Mannheim (Germany) - Department of Anaesthesiology and Critical Care Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration