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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Grietje Beck

Contact details
University Clinic Mannheim
Department of Anaesthesiology and Critical Care Medicine
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167
grietje.beck@anaes.ma.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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-Komission II: Medizinische Fakultat Mannheim der Ruprechts-Karls-Universitat Heidelberg) on the 22nd November 2007 (ref: 2007-258N-MA)

Study design
Observational study until 48 hours after surgery

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Secondary outcome measures
Elevation of inflammation markers, measured over 48 hours.

Overall study start date
01/02/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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

Sponsor details
Theodor-Kutzer-Ufer 1-3
Mannheim

Germany
68167
marc.schmittner@anaes.ma.uni.heidelberg.de

Sponsor type
Hospital/treatment centre

Website
http://www.klinikum-mannheim.de/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration