

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

<b>Submission date</b> 12/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/03/2008	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**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-Kommission II: Medizinische Fakultät Mannheim der Ruprechts-Karls-Universität 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**

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**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