ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Now Available for Public Comment: Notice of Proposed Rulemaking (NPRM) for FDAAA 801 and NIH Draft Reporting Policy for NIH-Funded Trials

Trial record 1 of 1 for: hemaclear

Previous Study | Return to List | Next Study

Neurologic Examination of Wide and Narrow Tourniquets (HEM)

This study has been completed.

Sponsor:
Medical University of Vienna

Information provided by (Responsible Party):
Dr. Florian M Kovar, Medical University of Vienna

ClinicalTrials.gov identifier:
NCT02023476

First received: December 17, 2013
Last updated: January 9, 2014
Last verified: January 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Nerve injury is a serious potential complication associated with the clinical use of exsanguinating tourniquets in surgery. Recently, a novel narrow tourniquet has been proposed, with the claim that it may cause less compression of the nerves. We performed an in vivo comparison of a standard wide tourniquet with the new, narrow tourniquet. Our study specifically looked at neurologic markers in the upper extremity.

Condition	Intervention
Nerve Compression	Radiation: MRI

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Crossover Assignment
Masking: Open Label

Official Title: Nerve Function in Healthy Human Volunteers With Two Different Tourniquets

Further study details as provided by Medical University of Vienna:

Primary Outcome Measures

- Nerve compression [Time Frame: 20 Minutes] [Designated as safety issue: No]
  mg/mm2

Secondary Outcome Measures

- Nerve compression [Time Frame: 20 minutes] [Designated as safety issue: No]

Enrollment: 18
Study Start Date: April 2010
Study Completion Date: September 2010
Primary Completion Date: September 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: wide tourniquet (Zimmer A.T.S.® 3000) wide tourniquet MRI intervention	Radiation: MRI MRI- imaging on the upper arm

Active Comparator: narrow tourniquet HemaClear ™ tourniquet MRI intervention	Radiation: MRI MRI- imaging on the upper arm

Detailed Description:
The HemaClear ™ OHK Medical Device HemaClear™, approved by FDA, consists of a silicon ring wrapped in a stockinet sleeve and pull straps (Fig.1). It performs three functions - blood removal (exsanguinations), arterial flow occlusion, and placement of sterile stockinet 30. The ring is placed on the extremity and then straps are pulled proximally. The silicone ring rolls up the limb while the stockinet sleeve unfolds onto the limb. During the rolling up process, the ring exerts pressure and squeezes the blood away from the limb. Application of the device takes less than a minute.

The technique behind this device is fundamentally different from classic pneumatic tourniquets, as pressure is exercised by only a single silicon ring so that the profile is very small.

Zimmer A.T.S.®3000 The A.T.S.®3000 is an automatic broad tourniquet system with a Limb Occlusion Pressure (LOP) feature. It is the latest innovation in tourniquet technology and has FDA approval. It was invented by McEwen 4 and the basic function is described in several clinical trials and publications 28. The main difference to other pneumatic tourniquets is the LOP and the Recommended tissue pressure (RTP) feature. These parameters are suitable to optimize the pressure force on the tourniquet for each individual patient. The LOP is detected before inflating the tourniquet and the RTP is the LOP plus a safety margin to guarantee a blood free field (Operator & Service Manual Zimmer A.T.S.® 3000 Automatic tourniquet system REF 60-3000-101-00).

Eligibility

Ages Eligible for Study: 18 Years to 45 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria
Inclusion Criteria:

- self defined Caucasian
- clinically healthy
- BMI of ≤ 30,
- a systolic arterial blood pressure ≤190 mmHg,
- no rash or dermatologic condition or tattoos which may interfere with the placement site
- no neurovascular impairment
- all female participants received a pregnancy test at the initial screening visit
- Study population was restricted to Caucasians to enable an assessment of device caused redness or skin lesions, not possible in a mixed study population.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02023476

Locations

United States, Maryland

RIAO, Sinai Hospital Baltimore
Baltimore, Maryland, United States, 21215-5271

Sponsors and Collaborators

Medical University of Vienna

Investigators

Principal Investigator: Florian M Kovar, MD: MUW

More Information

No publications provided

Responsible Party: Dr. Florian M Kovar, Univ. Lektor Dr. med. univ., Medical University of Vienna