Trial Description

Title

Platelet function assessed via Multiplate® and thrombomiR in patients with traumatic brain injury receiving aspirin: a prospective, observational pilot study.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In case of traumatic injury, patients undergoing platelet inhibition receive computed tomography and hospitalisation in order to exclude intracerebral hemorrhage.
Former data suggest variable specifity of inhibition in platelet function in patients undergoing platelet inhibition. The effect of administered drugs cannot be assesed via standard labaratory tests. It takes specific determination via Multiplate to get an idea of the range of impaired platelet function.

The aim of the study is to find out whether incidence and progression of traumatic intracranial haemorrhage in patients undergoing therapy with aspirin correlates with
findings in impaired platelet function detected using Multiplate® analyser and thrombomiR.

Brief Summary in Scientific Language

Platelet inhibition improves prognosis in patients suffering from acute coronary syndrome and is recommended for prophylaxis of stent thrombosis following percutaneous
transluminal coronary angioplasty (PTCA). Furthermore, current data suggest dual platelet
inhibition to prevent from stroke after transient ischemic attack (TIA) and minor stroke.
In consideration of the ageing trauma population, we have to face up to an increasing
number of patients undergoing platelet inhibition being examined in emergency departments after traumatic brain injury. Reduced platelet activity due to antiplatelet
therapy correlates with progression in intracerebral haemorrhage in patients with stroke.
Data regarding traumatic brain injury in those patients are missing so far.
Current guidelines for initial management in traumatic brain injury (TBI) recommend cranial
computed tomography (CCT) for early diagnosis of potential bleeding events in patients

**undergoing platelet inhibition.There is lack of data concerning the optimum point in
time for the follow-up CCT scans in this patient group. The authors point out that recommendations are up to an expert consensus. Daily clinical practice may vary according
to expert knowledge of the treating medical centre, availability of diagnostic tools and
clinical presentation of the patient.
According to recent studies a considerable percentage of patients present with drug
resistance to clopidogrel and/or aspirin. Hence, stratification of the individual patient´s
risk could be facilitated by monitoring platelet function.
Platelet function cannot be assessed by standard laboratory parameters (e.g. activated
partial thromboplastin time, prothrombin time, fibrinogen, platelet count). Multiple
electrode impedance aggregometry (MEA, Multiplate®) as a diagnostic tool in assessment of
platelet function is conversant with the monitoring of antiplatelet medication.To be
classified as a “point of care monitoring” system, it allows rapid assessment of antiplatelet
agent activity and evaluation of haemostatic measures on platelet activity.
Thrombomir analyzes a number of selected microRNAs associated with platelet activation and its results have been shown to correlate with other platelet function tests in patients on antiplatelet therapy. The potential advantage is that this readout of platelet function is very sensitive and independent of a specific platelet activation pathway
The aim of the study is to find out whether incidence and progression of traumatic intracranial haemorrhage in patients undergoing antiplatelet therapy with aspirin correlates with
findings in impaired platelet function detected using Multiplate® analyser and thrombomiR.**

ThrombomiR testing was not part of the initial study protocoll. Adjustments for number of participants, taken blood volume and statistical analysis have been approved by the ethics committee on 2017/01/09.

Organizational Data

- DRKS-ID: **DRKS00006036**
- Date of Registration in DRKS: **2014/04/02**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2159/2013 , Medizinische Universität Wien**

Secondary IDs

Health condition or Problem studied

- ICD10: **S06 - Intracranial injury**

Interventions/Observational Groups

- Arm 1: **target group: patients undergoing antiplatelet therapy with Aspirin and traumatic brain injury**

  Intervention:
  assessment of platelet function via Multiplate and thrombomiR in addition to standard labaratory parameters; single blood sampling (4,4ml)

  Intervention INDEPENDENT from the trial: cranial computed tomography (CCT) ad admission to the hospital and - in case of positive findings - repeated during hospital stay

  Aim of the study: corellation of incidence and progression of cranial bleeding and results of Multiplate and thrombomiR measurements

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

correlation between incidence/progression of traumatic intracranial haemorrhage in patients undergoing dual antiplatelet therapy and findings in impaired platelet function detected using Multiplate® analyser and thrombomiR testing

Secondary Outcome

none

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Wien**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/01**
- Target Sample Size: **160**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

positive findings in medical history regarding intake of acetylsalicylic acid (T-Ass®)

clinical evidence of traumatic brain injury (GCS 4 – 14)

Exclusion criteria

platelet count < 100G/l
life expectancy < 12h
surgical evacuation, intake of any other platelet inhibitor than aspirin

Addresses

- **Primary Sponsor**

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  Währinger Gürtel 18-20

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*