***PLEASE NOTE:*** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Tryptophan immunoadsorption as escalation therapy for multiple sclerosis relapse - documentation of efficacy**

### Trial Acronym

**TRIAS**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**For steroid-refractory multiple sclerosis (MS) relapses immunoadsorption (IA) and plasma exchange (PE) are recommended in neurological guidelines. Based on published data IA is at least equivalent to PE for steroid-refractory MS attacks regarding improvement of neurological symptoms. IA is a selective technique for extracorporeal removal of antibodies and immune complexes in contrast to non-selective PE with the disadvantegous need of substitution using human plasma products. Aim of this multicenter non interventional and retrospective study is to increase evidence of the clinical use of IA as escalation therapy for MS relapse by analyzing at least 100 patients.**

### Brief Summary in Scientific Language

**Standard treatment for Multiple sclerosis (MS) relapse is the intravenous administration of high doses of steroids for 3-5 days. For patients who do not or not satisfactorily respond to steroid pulses PE or IA are strongly recommended as escalation therapy in national and international guidelines. PE is a non-selective apheresis method with elimination of the entire plasma and the need of substitution using human plasma products. Protein replacement fluids, human albumin or fresh frozen plasma harbor as blood products allergic reactions as well as the risk of infection with virus or with yet unknown pathogens. During IA patient´s plasma is not discarded but flows through the adsorber where removal of antibodies and immune complexes takes place. The treated plasma is then combined with the blood cells and reinfused to the patient. Efficacy of IA with the tryptophan adsorber as escalating therapy for MS relapse has been reported in several publications, suggesting that IA is at least equivalent to PE for steroid-refractory MS attacks without the disadvantageous need of substitution. Yet clinical data of a larger study population were warranted to confirm these results. Aim of this retrospective non interventional mutlicenter study is to increase evidence of the clinical use of tryptophan IA as escalation therapy for MS relapse.**

## Organizational Data

- DRKS-ID: **DRKS00010099**
- Date of Registration in DRKS: **2016/02/25**
- 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.: **014/1364 , Freiburger Ethik-Kommission International**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G35 - Multiple sclerosis**

## Interventions/Observational Groups

- Arm 1: **All patients treated with tryptophan immunoadsorption for MS relapse as part of their standard medical care are analysed.**

## Characteristics

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

### Primary Outcome

**Main outcome parameter for efficacy of immunoadsorption is change of acute ms relapse related disability. Clinical evaluation is performed before the first IA and after the last IA of the treatment series. Functional MS-related disability will be assessed with the EDSS (expanded disability status scale). In patients with optic neuritis also the best corrected visual acuity will be used.**

### Secondary Outcome

**Tolerability and safety of immunoadsorption. IA treatments will be documented in CRF´s. Parameter for safety and tolerability are: blood pressure, vascular access, fibrinogen concentration, treated plasma volume, general condition of the patient.**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Asklepios Fachklinikum, Teupitz**
- Medical Center **Fachkrankenhaus Hubertusburg, Wermsdorf**
- Medical Center **Klinikum Lüdenscheid, Lüdenscheid**
- University Medical Center **Universitätsklinikum, Jena**
- University Medical Center **Charité Universitätsmedizin, Berlin**
- Medical Center **Klinikum Martha-Maria, Halle Saale**
- other **Apherese Forschungsinstitut, Köln**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/06/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

**Additional Inclusion Criteria**

**acute MS relapse with indication for escalation therapy with immunoadsorption**

**Exclusion criteria**

**Patient doesn´t agree to participate. Treating physician doesn´t want to participate in the investigation**

## Addresses

- **Primary Sponsor**

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## Sources of Monetary or Material Support

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

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/31**

## 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.*