Trial Description

Title

Double-blind, randomised, placebo-controlled prospective multi-centre phase III trial to assess the efficacy and safety of methanthelinium bromide (Vagantin®) in the treatment of focal palmar-axillary hyperhidrosis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Evaluation of the efficacy and safety of Vagantin® in comparison to placebo in the treatment of excessive sweating under armpits and on hands

Brief Summary in Scientific Language

Evaluation of the efficacy and safety of Vagantin® (methanthelinium bromide) in comparison to placebo in the treatment of axillary-palmar hyperhidrosis

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000474**
- Date of Registration in DRKS: **2010/07/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **ZS EK 10 550/08 , Ethik-Kommission des Landes Berlin**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1115-8816**
- EudraCT-Number: **2007-007055-13**
- BfArM-No.: **4034789**

Health condition or Problem studied

- ICD10: **R61 - Hyperhidrosis**

Interventions/Observational Groups

- Arm 1: **Vagantin 150 mg / day**
- Arm 2: **Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

axillary sweat gravimetry (mean of both axillae) on day 28 +/- 1

Secondary Outcome

- **axillary sweat gravimetry on day 14 +/- 1**
- **palmar sweat gravimetry on days 14 +/- 1 and 28 +/- 1**
- **hyperhidrosis disease severity scale (HDSS) on days 14 +/- 1 and 28 +/- 1**
- **dermatology life quality index (DLQI) on days 14 +/- 1 and 28 +/- 1**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/06/13**
- Target Sample Size: **336**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

• male and female patients, aged 18-65 years
• Caucasian origin
• focal hyperhidrosis (axillary or focal palmar-axillary, > 50 mg/5min both axillae and > 50 mg/5min both palms – palmar hyperhidrosis will only be assessed, if the condition >50 mg/5min is fulfilled)
• duration of clinically manifested hyperhidrosis for at least 1 year
• failure of at least one topical treatment course
• written informed consent given by patient after being provided with detailed information about the nature, risks, and scope of the clinical trial as well as the expected desirable and adverse effects of the drug
• female subjects of childbearing potential willing to use contraception during the study period (i.e. abstinence, oral contraception, intrauterine device, diaphragm, condom, spermicide, implant contraception, systemic contraception) or have secondary infertility or whose partner had a vasectomy, or female subjects of non childbearing potential (i.e. had hysterectomy, bilateral ovariectomy, tube ligation) or are post-menopausal defined as absence of menstrual bleeding for 1 year, or 6 if laboratory confirmation of hormonal status

Exclusion criteria

• secondary axillary hyperhidrosis
• hidrosadenitis axillaris/inguinalis
• prior surgery of perspiratory glands or endoscopic thoracic sympathectomy
• iontophoresis < 6 months or botulinum toxin treatment < 12 months prior

- **other concomitant medication which would interfere with trial medication as antiperspirants (e.g. topical application of aluminium chloride 15% – 30% dilution), diaphoretics, anticholinergics (bornaprine hydrochloride), Antihistaminics, ß-sympathomimetics, amantadine , tricyclic antidepressants, chinidine, disopyramide,**
last intake at least 8 weeks respectively 10 half-lives of the respective drugs
- **concomitant procedures which would interfere with trial medication as iontophoresis, liposuction-curettage, local excision, endoscopic thoracic sympathectomy**
- **mechanical stenosis in the gastro-intestinal tract, severe chronic inflammatory intestinal disease or toxic megacolon**
- **urinary retention in the case of prostate adenoma or other subvesical obstruction**
- **narrow-angle glaucoma**
- **tachycardia or cardiac arrhythmia**
- **myasthenia gravis**
- **renal insufficiency or pre-existing severe liver disease**
- **spicy meals before gravimetric measurements**
- **patients with hereditary fructose or galactose intolerance**
- **patients with hereditary glucose galactose malabsorption (GGM)**
- **patients with congenital lactase or saccharase-isomaltase defect**

- **known contraindication for study medication (or any of the excipients contained in the product, i.e. sunset yellow S, lactose, sucrose)**
- **unreliability and/ or lack of cooperation, evidence of non-compliance**
- **current or previous participation in another clinical trial within prior 12 weeks**
- **pregnancy or lactation in female patients**
- **signs of clinically relevant illness or mental illness**
- **history of or current alcohol or drug abuse**
- **other objections which avoid the participation in the study in the opinion of the investigator**
- **persons committed officially or legally to an institution**
- **legal incapacity and/or other circumstances rendering the patient able to understand the nature, scope and possible consequences of the study**

Addresses

■ **Primary Sponsor**

RIEMSER Arzneimittel AG
Mr. Dr. med. Berno Müller
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

Telephone: **0751 - 35 90 59 52**
Fax: **038351 - 76 77 8**
E-mail: **dr.mueller at riemser.de**
URL: **www.riemser.com**

■ **Contact for Scientific Queries**

Division of Evidence Based Medicine dEBM
Klinik für Dermatologie

Contact for Scientific Queries

Charité - Universitätsmedizin Berlin
Mr. Prof. Dr. med. Berthold Rzany
Charitéplatz 1
10117 Berlin
Germany

Telephone: **030 - 450 518 283**
Fax: **030 - 450 518 927**
E-mail: **berthold.rzany at charite.de**
URL: **[---]***

- **Contact for Public Queries**

Division of Evidence Based Medicine dEBM
Klinik für Dermatologie
Charité - Universitätsmedizin Berlin
Mr. Prof. Dr. med. Berthold Rzany
Charitéplatz 1
10117 Berlin
Germany

Telephone: **030 - 450 518 283**
Fax: **030 - 450 518 927**
E-mail: **berthold.rzany at charite.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

RIEMSER Arzneimittel AG
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

Telephone: **038351 - 76 0**
Fax: **038351 - 76 778**
E-mail: **info at riemser.de**
URL: **www.riemser.com**

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*