PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Phase IIb Study on the Safety and Efficacy of BM32, a Recombinant Hypoallergenic Vaccine for Immunotherapy of Grass Pollen Allergy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The study will evaluate the efficacy and safety of BM32 in grass pollen allergic subjects.
It will test the hypothesis that either of two doses of BM32 will lead to a sustained relief
off allergy symptoms over a two year study period.

Brief Summary in Scientific Language

The present study is designed to evaluate the efficacy and safety of a treatment with the
recombinant vaccine BM32 during two consecutive grass pollen seasons. Efficacy evaluation
will be performed on the basis of allergy symptoms and use of relief medication as well as
based on immunological parameters. After patient assessment during a screening season,
patients will be randomized to one of two doses of BM32 or placebo. Patients will receive
three injections of BM32 pre-season and one post-season boost injection to maintain optimal
allergen specific IgG responses. Outcome will be measured after both seasons individually.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005543**
- Date of Registration in DRKS: **2014/08/22**
- Date of Registration in Partner Registry or other Primary Registry: **2012/02/07**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2012-000442-35**
- Primary Registry-ID: **NCT01538979 (ClinicalTrials.gov)**
- Sponsor-ID: **CS-BM32-003 (Biomay AG)**
- Other Secondary-ID: **2012-000442-35**

Health condition or Problem studied

- Free text: **Grass Pollen Allergy**
- ICD10: **J30.1 - Allergic rhinitis due to pollen**

Interventions/Observational Groups

- Arm 1: **Biological: BM32**
- Arm 2: **Biological: BM32**
- Arm 3: **Biological: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Mean daily combined symptom medication score (SMS)during the peak of the pollen season.; time frame: Up to 3 months; The score will be recorded daily for the 30-45 days with the highest pollen count in each center

Secondary Outcome

- Vital functions; time frame: Up to 22 months
- Safety laboratory hematology; time frame: up to 22 months
- Meal level of "well-being" measured by a visual analog scale (VAS) during grass pollen season; time frame: Up to 8 months; The VAS will be recorded daily during the grass pollen seasons of 2013 and 2014
- Number of "bad days" during the peak pollen season and the whole pollen season; time frame: Up to 8 months; The number of bad days will be recorded daily during the grass pollen seasons of 2013 and 2014
- Number of symptom-free days during the peak pollen season and the whole pollen season; time frame: Up to 8 months; The mesure will be recorded daily during the grass pollen seasons of 2013 and 2014
- Rhinoconjunctivitis quality of life evaluation by RQLQ questionnaire during pollen season; time frame: Approx. 22 months; The questionnaire will be completed on a weekly basis during the pollen seasons of 2013 and 2014.
- Mean asthma score during pollen season; time frame: Up to 8 months; The score will be recorded on a daily basis duirng the pollen seasons of 2013 and 2014
- Mean allergy specific IgG and IgE antibodies before and after vaccination; time frame: Up to 16 months; These antibody levels will be recorded a total of five times (01/2013, 04/2013, 09/2013, 01/2014 and 04/2014)
- Mean daily symptom and medication score during the whole pollen season; time frame: Up to 8 months; The score will be recorded daily approximately during May 2013 - August 2013 and May 2014 - August 2014
- Mean daily symptom score (SS) and medication score (MS) during the peak pollen season and the whole pollen season; time frame: Up to 8 months; The scores will be recorded daily during the pollen seasons of 2013 and 2014
- Skin reactivity to grass pollen extract by titrated skin prick testing; time frame: Up to 15 months; The titrated skin prick testing will be applied a total of 4 times before and after the pollen seasons of 2013 and 2014.

- Results of physical examination; time frame: up to 22 months
- Safety Laboratory: Blood biochemistry; time frame: Up to 22 months
- Safety laboratory: Urine analysis; time frame: up to 22 months

Countries of recruitment

- AT **Austria**
- BE **Belgium**
- DK **Denmark**
- DE **Germany**
- NL **Netherlands**
- SI **Slovenia**

Locations of Recruitment

- **Department of Dermatology and Allergology Am Biederstein TU Munich, Munich**
- **Allergiezentrum Charite, Berlin**
- **Klinik und Poliklnik für Dermatologie und Allergologie der Universität Bonn, Bonn**
- **Dept. of Dermatology and Allergology University Medical Center Gieseen and Mrbaurg GmbH, Marburg**
- **Zentrum für Rhinologie/Allergologie, Wiesbaden**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/03/31**
- Target Sample Size: **180**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

- Positive history of grass pollen allergy

- Positive skin prick test reaction to grass pollen extract

- Grass pollen specific IgE and rPhl p 1/rPhl p 5 specific IgE (>3 kUA/L)

- Moderate to severe symptoms of grass pollen allergy during pollen peak

Exclusion criteria

- Symptomatic perennial allergies

- Atopic dermatitis

- Pregnancy or breast feeding

- Women with childbearing potential not using medically accepted birth control

- Autoimmune diseases, immune defects, immune suppression

- Immune complex induced immunopathies

- Contra indications for adrenaline

- Severe general maladies, malignancies

- Patients on long-term systematic corticosteroids, immune suppressive drugs, tranquilizers or psychoactive drugs

- Contra indication for skin prick testing

- Bronchial asthma not controlled by low dose inhaled corticosteroids

- Chronic use of beta blockers

- Participation in another clinical trial within one month prior to study

- Participation in SIT trial in 2 years prio to study

- Patients who had a previous grass pollen SIT

- Risk of non-compliance with study procedures

- Use of prohibited medications

- Depot corticosteroids - 12 weeks prior to enrolment

- Oral corticosteroids - 8 weeks prior to enrolment

- High dose inhaled corticosteroids - 4 weeks prior to enrolment

- Use of H1 antihistamines 3 days prior to enrolment

Addresses

- **Primary Sponsor**

  Biomay AG

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Technical University Munich, Klinik und Poliklinik für Dermatologie and Allergologie
  Johannes Ring, Prof. Dr. Dr.

  Telephone: **[---]***
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  URL: **[---]***

- **Contact for Public Queries**

  Angela Neubauer, PhD

  Telephone: **+43-1-7966-296**
  Fax: **[---]***
  E-mail: **a.neubauer at biomay.com**
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

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

Deutsches Register Klinischer Studien
German Clinical Trials Register

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 1

- Last processed date by ClinicalTrials.gov: 2013/12/01

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.