

# Birch Associated Soy Allergy and Immuno-Therapy

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| <b>Submission date</b><br>03/08/2009   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>27/08/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/08/2019       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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Germany  
04103

## Additional identifiers

**Protocol serial number**  
1-2009

## Study information

### Scientific Title

A multicentre randomised placebo-controlled double-blind clinical trial for the evaluation of efficacy of specific immunotherapy (SIT) with an aluminium hydroxide-adsorbed recombinant hypoallergenic derivative of the major birch pollen allergen r Bet v1-FV on Bet v 1 associated soy allergy

**Acronym**

BASALIT

### **Study objectives**

To determine the efficacy of specific subcutaneous immunotherapy (SCIT) against birch allergen Bet v 1 on birch pollen associated soy allergy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Prospective double blind randomised multicentre two-armed therapy trial; phase IIb

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Immediate type allergy to soy proteins in patients with birch pollinosis

### **Interventions**

Specific subcutaneous immunotherapy with extract containing either main Birch allergen Bet v 1 or placebo (randomisation 2:1), duration: 1 year, no follow up.

### **Intervention Type**

Other

### **Phase**

Phase II/III

### **Primary outcome(s)**

Threshold dose of soy protein leading to first symptoms at DBPCFC (lowest observed adverse effect level - LOAEL); two primary endpoints (without hierarchy) - LOAELobj for clinically objective and LOAELsubj for subjective symptoms. Timepoints: baseline 9 months - 1 week before intervention, control: 2 weeks - 5 months after intervention.

### **Key secondary outcome(s)**

1. Skin prick test to soy. Timepoint: baseline 9 months - 1 week before intervention, control: at end of intervention (week 50 - 52 of intervention).
2. Food allergy related quality of life. Timepoint: baseline 9 months - 1 week before intervention, control: at end of intervention (week 50 - 52 of intervention).
3. Specific IgE and IgG4 against Bet v 1, Gly m 4, Cor a 1, Mal d 1, Pru Av 1, Cau c 1, Api g 1. Timepoint: baseline at start of intervention, control at week 12, 18, 30, 50 - 52 of intervention.
4. T-cell reactivity to Bet v 1 and Gly m 4. Timepoint: baseline at start of intervention, control at week 18 and 50 - 52.

### **Completion date**

## Eligibility

### Key inclusion criteria

1. Male or female adult patients aged 18 - 65 years inclusive, legally competent
2. Informed consent
3. History of spring pollinosis for at least 2 years
4. Sensitisation to birch pollen as demonstrated by positive SPT to birch (wheal greater than 3 mm)
5. Specific IgE for Bet v 1 and Gly m4 (both greater than ImmunoCAP class 1
6. Clinical relevance of Gly m4 sensitization as demonstrated by positive food challenge (DBPCFC) to soy proteins
7. For female patients: effective contraception and negative pregnancy test result

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

56

### Key exclusion criteria

1. SIT against birch within last 5 years
2. Pregnancy, lactation period or female patients seeking to become pregnant
3. Peak expiratory flow (PEF) or forced expiratory volume in one second (FEV1) less than 80% of predicted normal (ECCS) or
4. Uncontrolled bronchial asthma according to Global Initiative for Asthma (GINA) 2006
5. Febrile infections or inflammation of the respiratory tract at the time of inclusion
6. Irreversible secondary lung alterations (i.e. emphysema, bronchiectasia)
7. Severe acute or chronic diseases, severe inflammatory diseases
8. Other severe generalised diseases (liver, heart, kidney, metabolic disorders)
9. Autoimmune diseases, immune defects including immunosuppression, immune-complex induced immunopathies
10. Severe psychiatric and psychological disorders including impairment of cooperation (e.g. alcohol or drug abuse)
11. Completed or ongoing long-term treatment with tranquilizer or psycho-active drugs
12. Short time therapy with oral glucocorticosteroids is possible under certain circumstances
13. Concurrent participation in any other clinical trial or participation in any other clinical trial

during the previous 30 days

14. Low compliance or inability to understand instructions/study documents

15. Patients who have been committed to a mental hospital by government or court

16. Completed or ongoing treatment with anti-IgE antibody

17. Patients being in any relationship or dependence with the sponsor and/or investigator

18. Contraindication for adrenaline, (e.g. acute or chronic symptomatic coronary heart disease, severe arterial hypertension)

19. Therapy with betablockers topically or systemically

20. Patient's withdrawal of consent

**Date of first enrolment**

01/10/2009

**Date of final enrolment**

31/03/2013

## **Locations**

**Countries of recruitment**

Germany

Switzerland

**Study participating centre**

Ph.-Rosenthal-Str. 23

Leipzig

Germany

04103

## **Sponsor information**

**Organisation**

University of Leipzig (Germany)

**ROR**

<https://ror.org/03s7gtk40>

## **Funder(s)**

**Funder type**

Government

## Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 01/08/2017   | 08/08/2019 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |