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Birch Associated Soy Allergy and Immuno-Therapy

Submission date	Recruitment status	[X] Prospectively registered
03/08/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2019	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

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

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 invervention, 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

31/03/2013

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, bronchiektasia)
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?
Results article	results	01/08/2017	08/08/2019	Yes	No