

Informed consent: Subcutaneous Specific Immunotherapy (SIT)

Dear patient,

It is the aim of specific immunotherapy (SIT) to reduce allergic reactions against allergens. To do so, well defined amounts of modified allergens are applied subcutaneously following a specific time-schedule.

Fulfilling this time-schedule and the doctor's advice will increase efficacy and safety of the treatment.

SIT is useful for allergens that cannot be completely avoided e.g.: grass-, tree-, weeds-pollen, house-dust mite and insect-venoms. Indications for SIT against mould or animal-dander have to be set very strictly (reduced standardisation, safety and efficacy data).

SIT against **perennial allergens** (e.g. house dust mite, insect-venom, animal dander) usually has to be done at least over 3 years. In the beginning vaccinations will be given every week, later every month.

Presaisonal SIT is used in **seasonal allergens** like pollen. Generally the first doses will be applied weekly, followed by monthly applications over 3 seasons. Your doctor will show you the exact time-schedule for your SIT.

Your compliance is absolutely necessary!

Important issues:

- Intervals for first vaccinations should not be less than 7 days and not more than 14 days.
- Other vaccinations (influenza etc.) should not be applied within a week prior/ after SIT.
- Avoid unusual physical stress within 24 hours after vaccination
- Tell your doctor how you tolerated your last vaccination.
- Tell your doctor, if you are healthy or not at time of vaccination (If you had fever within the last week before vaccination, the SIT will be postponed).

If you have allergic symptoms at time of vaccination or you had side-effects after the last SIT, or the vaccination interval has changed, the doctor will adjust your vaccination-dose.

Possible side-effects or complications:

No medical treatment is free of risks. The following risks are known for SIT:

- common: itchiness, reddening or swelling at the site of vaccination.
- rare: red spots, urticaria on the whole body, rhinitis, conjunctivitis, granuloma (persisting nodule at vaccination-site)
- extremely rare: breathing-difficulties, acute asthma, circulation problems (low blood-pressure), unconsciousness, allergic shock.

Severe complications usually turn out within the first 30 minutes after vaccination. Therefore you have to stay for this time in our allergy-centre for further surveillance. If other symptoms occur after this time, please contact your doctor or use the emergency call.

Success rate

The success rate depends on various factors, like your specific allergen-profile and compliance.

Depending on the allergen, we can reach an improvement of the patients' symptoms in about 80%. Best chances are for patients with insect-venom allergies, followed by pollen allergies and house dust mite allergy.

In some patients symptoms disappear, in others they are significantly reduced. Some studies also showed that in some patients new sensitisations and asthma can possibly be prevented by SIT.

We observe a variable development of symptoms of a cross-reaction to food-allergens. In some patients symptoms initially worsen (please avoid specific food if this is the case), in others they improve during SIT.

Please ask your doctor if you have any other questions. It is our concern that you are well-informed.

Consent:

I have been informed about efficacy and possible side-effects of specific immunotherapy (in written and oral form) by the doctor and have no further questions. I therefore agree to the therapy.

_____. _____
day month year

Patient's signature (or legal guardian)

Doctor's signature

If one parent signs the consent-form, he declares that he has the exclusive child custody or that he acts in agreement with the other parent.

Children under 14 years of age must be accompanied by an adult for each vaccination!