VITESSE

VITESSE study fact sheet

A quick reference guide to use in discussions with potential VITESSE study parents/caregivers

Thank you for your interest in learning about the VITESSE study. This fact sheet provides more details about the study that you can share with parents/caregivers. If parents/caregivers have any questions or would like to know more, please direct them to scan the QR code or call the local study site at the number below.

What is the VITESSE study?

The VITESSE study is evaluating an investigational drug patch called DBV712 for children 4 to 7 years of age with peanut allergy. The main purpose of this study is to learn how well the investigational drug (also called study drug) patch (DBV712) works and how safe it is compared with a placebo patch in children with peanut allergy. The small amount of peanut protein in the study drug patch is designed to potentially desensitize (or make less sensitive) a peanut-allergic person by repeated exposures to very small amounts of peanut.

Who is this study enrolling?

This study is for children 4 to 7 years of age who have been diagnosed with peanut allergy and are currently following a strict peanut-free diet.

Why is this study important?

Peanut allergy is one of the most common food allergies in children. The reaction after exposure to peanuts is usually immediate and can be severe or even life threatening. Researchers continue to study peanut allergy and test different study drugs for children who are in need of additional effective therapies.

How are the study drugs being tested?

Eligible participants will be randomly assigned (by chance) to receive the study drug (DBV712) patch or placebo patch. Participants will have about a 67% (2 in 3) chance of receiving the DBV712 patch and about a 33% (1 in 3) chance of receiving the placebo patch. Participants, parents/caregivers, the study doctor, and study staff will not be told the assignment. However, this information will be given to the study doctor if it becomes necessary for the participant's safety.

After completion of the VITESSE study, participants may be offered the possibility to participate in an extension study. During the extension study, all participants will receive the DBV712 patch (regardless of their assignment in this study).

How long will this study last?

Parents/caregivers will be asked to attend at least 12 study visits with their child over a period of approximately 58 weeks (about 1 year). During this period, a study team member will also call parents/caregivers a minimum of 5 times in between visits to check on the participant.

How will participants' health be monitored in this study?

During the study, parents/caregivers will accompany the participant to the study site regularly for health checks and several types of tests and assessments. These may include:

- Physical examinations
- Vital signs measurements (body temperature, breathing rate, blood pressure, and heart rate)
- Lung function tests
- Peanut food challenges
- Skin assessments
- Blood tests
- Questionnaires

Not all of these activities will occur at every visit.

What are the benefits and risks of being in this study?

There is no guarantee that participants will receive any benefits from participating in this study. However, participants will be helping others with peanut allergy by contributing to medical research. Any study has risks, which may lead to the participant feeling sick or uncomfortable or could cause them harm. Also, as with all drugs, the study drug patch may cause side effects. The study staff will review potential risks with parents/caregivers before study enrollment.

Is participating in this study mandatory?

Taking part in a clinical study is voluntary. If a participant is eligible to enroll, a parent/caregiver may choose to have them join the study but leave at a later date for any reason at any time.

How can parents/caregivers learn more about the VITESSE study?

To learn more, please scan the QR code or call our local study site at the number below. The study team can schedule a screening appointment to explain the study in detail.

Study site phone number:

Beverley Ojeaga (Research Coordinator) +1 (236) 513-0383

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