STAND AGAINST DIABETIC FOOT ULCERS.

Step Up and Join a Study of an Investigational Herbal Cream Treatment.

Every day,
research uncovers new
information about medical
conditions and their treatment.
Volunteer involvement in clinical
studies is a key part in the
development and advancement
of future therapies. Results
collected from clinical studies
have led to thousands of
medications and devices
becoming available to
patients all over the world.

What is a clinical study?

A clinical study (also known as a clinical trial) is designed to learn more about a drug's ability to treat a specific disease or condition. Regulatory agencies use the results of clinical studies to decide if an investigational drug should be made available to patients and if changes should be made to how approved drugs should be prescribed.

Every clinical study is reviewed by an Institutional Review Board (IRB), which helps ensure that the study is conducted properly and that the rights of study participants are protected. Clinical studies are conducted by trained medical professionals who monitor the health of participants throughout the study.

Clinical studies are the only way we can develop new and better medical treatments and improve patient care.

What is the purpose of this study?

The main purpose of this study is to evaluate an investigational treatment for diabetic foot ulcers. The study drug is called ON101, a topical cream which consists of two herbal medicines: *Plectranthus amboinicus* (commonly known as Mexican mint) and *Centella asiatica* (also known as Asiatic pennywort). In previous studies, it was shown to promote wound healing and the growth of new blood vessels (angiogenesis).

Who can participate in this study?

You may qualify to participate if you:

- *Are 18-80 years of age*
- *Are being treated for type 1 or type 2 diabetes*
- *Have at least 1 foot ulcer that qualifies for the study*
- *Are able to walk but do NOT need to stand continuously for more than 4 hours per day*

Your medical history and other criteria will be checked to see if you can take part in the study.

What is involved in the study?

Approximately 208 people will be in the study at multiple research centers within the United States. Participation lasts 7-8 months, and while in the study, you will continue your regular treatments for diabetes. The study is divided into 3 main periods:

1	**Screening Period (2 weeks)**	You will have medical tests done and your medical history will be reviewed to find out if you can be in the study. This involves 2 visits, one week apart.
2	**Study Treatment Period (4½ months)**	If you continue to qualify, you will be randomly assigned (like flipping a coin) to 1 of 2 study treatment groups: ◦ Group A: Active study drug cream ◦ Group B: Placebo (foot cream without any active ingredient) You do not get to choose which group you are in and neither you nor the study doctor will know which group you are in unless there is an important medical reason to find out. You will apply the study treatment and fresh wound dressings twice each day and return to the clinic about every 2 weeks over the next 4½ months to check on your health and perform study-related tests. You will use a smart phone to take photos and keep track of dates and times of treatment applications and dressing changes. During this period, you will also need to wear an "off-loading device" when walking or standing. This is a special boot or shoe you wear to help keep weight off of your affected foot.
3	**Follow-up Period (3 months)**	After the end of study treatment, you will return to the clinic 4 more times over the next 3 months for additional study tests and to check on your health.

Should I participate in the study?

It is not known whether you will get any benefit from participating in this study. We do know that the information collected in this study will help the study sponsor and doctors learn more about this investigational treatment. This information may help future patients.

Taking part in a clinical study is completely voluntary. If you agree to participate and are enrolled in the study, you can choose to end your participation at any time and for any reason.

Will the study cost anything?

You will not have to pay for the study drug, wound dressing supplies, visits, or for the procedures needed for you to take part in this study. The sponsor of the study will pay for the costs of the study drug, as well as the costs of the tests and procedures needed in this study.

You or your insurance company will have to pay for procedures or tests that are part of the standard treatment for patients with your health problem.

How can I learn more about this study?

To ask questions or find out if you could participate, please contact:

Foot & Ankle Center of Illinois

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