

INSECT BITE STUDY

Conduct of a full-service single-center study

In 2019, the proderm Medical team took on a very challenging and unique project for a European medical device company. The objective was to evaluate the efficacy and safety of a medical device for the symptomatic treatment of insect bites. As a full service CRO, proderm developed a clinical trial design that leveraged our unique capabilities to fulfill the requirements and needs of the sponsor.

- Method Development
- Project Management
- Data Management
- Statistics
- Clinical Monitoring
- Volunteer Recruitment and Study Conduct
- Scientific Writing



Study specifications

- intra-individual
- randomized
- monocentric
- placebo-controlled
- (planned) randomizations:
26 healthy volunteers
- expected drop out rate: 30%
- primary parameter: assessment of itching over time via visual assessment scale

Our employees suck...

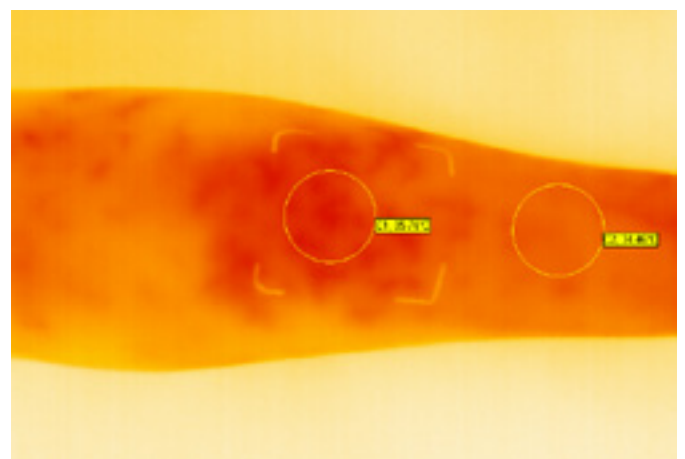
...blood! For this clinical trial, we complemented our excellent proderm team with some new colleagues: tiny, blood-sucking insects! In cooperation with a specialized provider of laboratory-grade mosquitos, we developed and implemented a system to reliably induce single mosquito bites on the volar forearms of human volunteers.



Secure handling of a mosquito

Documenting insect bite immune reaction

Clinical photography and imaging techniques are one of the fields proderm excels at. Mosquito bite wheals were photographically documented using high resolution digital photography in a reproducible set up. In order to visualize the immune response to insect bites, we measured skin surface temperature distribution using a thermal imaging camera.



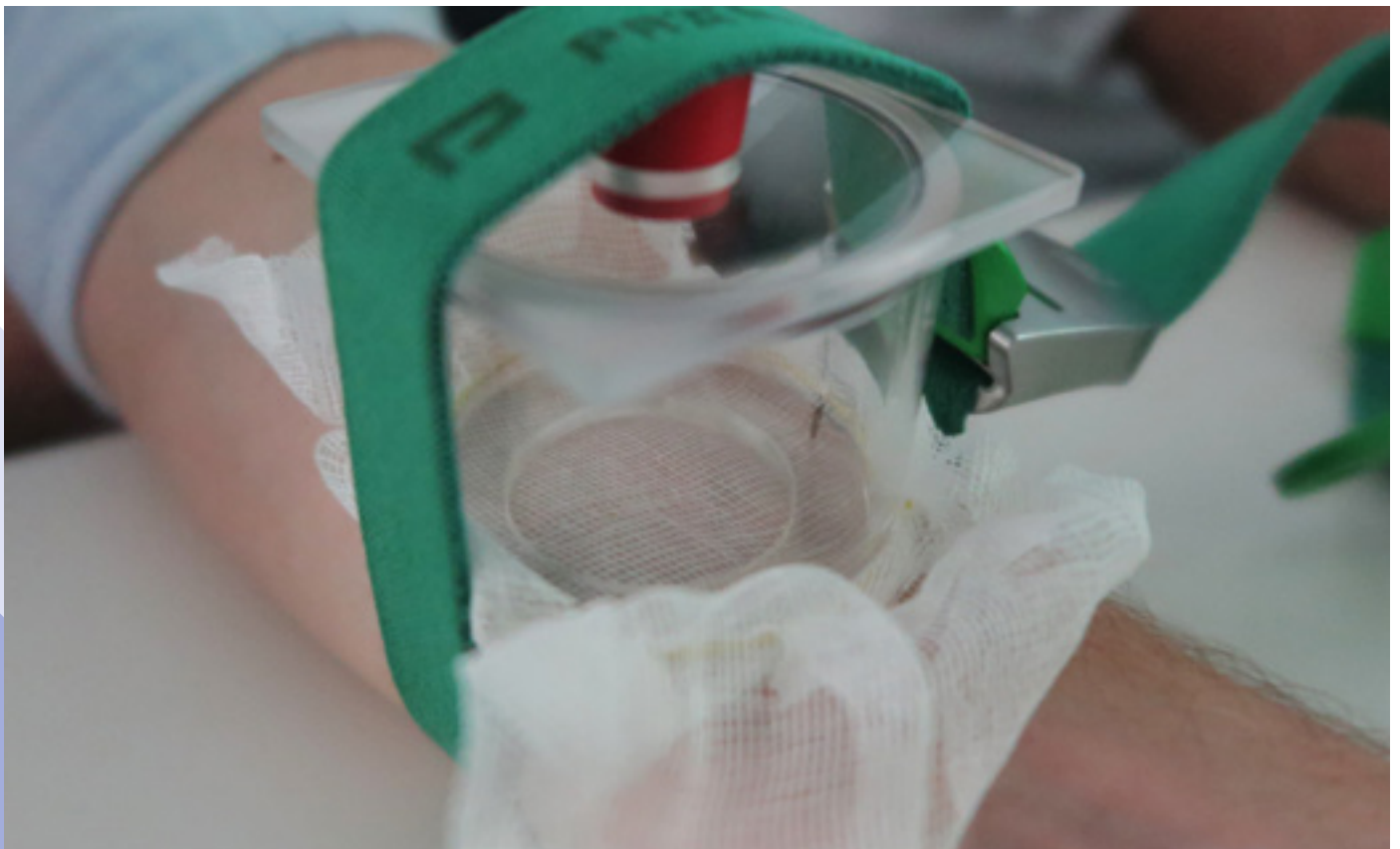
Thermograph of a mosquito bite taken with a thermal imaging camera (VarioCam hr head, Jenoptik, Jena, Germany).



Key challenges

Here are some of the key issues we solved developing the proderm insect bite model:

- Picking the appropriate insect for a safe clinical trial: Mosquitos
 - Mosquitos have comparably low anaphylactic potential
 - Lab-raised mosquitos do not carry infectious diseases
- Choosing the right mosquito to get the job done
 - Not all mosquito species are prone to bite under laboratory conditions - we found one that bites reliably and causes sufficient itching
- Providing the perfect conditions for our little friends!
 - As mosquito feeding behavior is highly seasonal and characterized by a narrow optimal temperature and humidity range, proderm created specific environmental settings in our climate controlled examination rooms for good biting conditions.
- Safe and reliable handling of mosquitos by trial staff
 - Not a single escaped mosquito! (we now call it „Mosquito Alcatraz“)



Laboratory-grade mosquito ready to feed



Study milestones

We were able to induce mosquito bites in clinical trial subjects under reproducible conditions.

The proderm Medical team correctly anticipated a drop out rate of around 30% due to the challenging criterion of a minimum itch response, which allowed us to meet the targeted number of completers for the analysis. Despite the unique study design, the submission was accepted by the ethics committee without any additional requirements.

Thanks to our carefully thought-out study set

up and very thorough training of our dedicated study staff, we were able to conduct this study without a single protocol deviation. An inspection of the local authority found absolutely no findings with the conduct of the study.

Our creative and tailor-made study design, as well as our excellent study conduct, resulted in clinical data supporting the market authorization of the product according to the MDR for the sponsor.

Sponsor feedback

„Always thinking in solutions, never in issues! The proactive and transparent communication made this project to a fantastic experience with a partner, who always found a solution and got the job done successfully in high quality and short time.“