Summary of clinical trial results for the public

Trial Information

Simple trial name: A clinical trial to compare the skin glues MAR-CUTIS and Dermabond Advanced in the closure of surgical cuts and wounds

Protocol number: KF7021-04

Trial sponsor: Grünenthal GmbH

Thank you to the trial patients

If you are a patient or parent/legal guardian of a patient who took part in the clinical trial, thank you for your time and commitment.

You made the clinical trial possible.

You helped us on our way to bringing new medicines to patients.

Important note: You should not use this summary to make decisions about the medical treatment you use. You should always see your doctor for advice about medical treatment.

About this summary

This summary is written to share the results of this clinical trial with the public. It is written in a way that should be easy for most people to understand. It describes why the trial was needed, how it was done, and the results.

General information about the clinical trial

Why was this trial needed?

MAR-CUTIS is a type of skin glue device designed to stick cuts and wounds on the skin made by a doctor during surgery. Skin glues are applied on surgical cuts and wounds with the help of a syringe. It joins the skin edges together for normal healing and protection against infections.

Other commonly used methods for joining skin edges together on surgical cuts and wounds are staples or stitches.

In this trial, researchers compared the effects of a device called MAR-CUTIS with Dermabond Advanced, an approved type of skin glue, on the closure of surgical cuts and wounds of participants.

Which devices were studied?

- **MAR-CUTIS (trial device)**: a type of skin glue syringe being tested for closing cuts and wounds after surgery.
- **Dermabond Advanced (reference device):** an approved type of skin glue syringe used for closing cuts and wounds after surgery or injury.

What was the main objective of the trial?

The main objectives of the trial were to find out:

- the effects of MAR-CUTIS and Dermabond Advanced in the closure of surgical cuts and wounds of participants.
- how many side effects were reported for participants treated with MAR-CUTIS compared with Dermabond Advanced.

When was the trial?

This trial started on 30 October 2018 and ended on 04 September 2019.

The sponsor ended this trial early. The initial results about the effects of MAR-CUTIS on the closure of surgical cuts and wounds were not as good as the effects of Dermabond Advanced. The method of assessing the

effects of these two devices on the closure of surgical cuts and wounds was not precise. The trial results were unclear. Even if the trial continued, the quality of the data would not have improved.

Where did this trial take place?

The trial took place in the following countries:

European Union (EU) countries

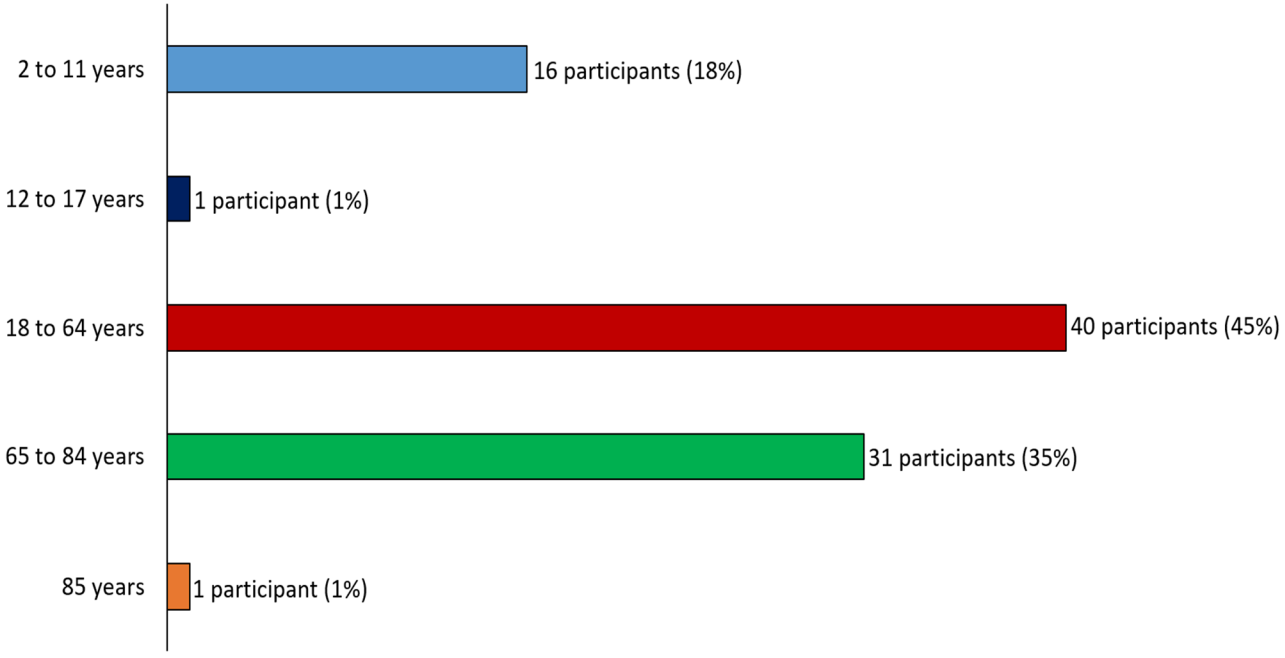
- United Kingdom (50 participants)
- Spain (23 participants)
- France (9 participants)
- Germany (7 participants)

Which participants were included in this trial?

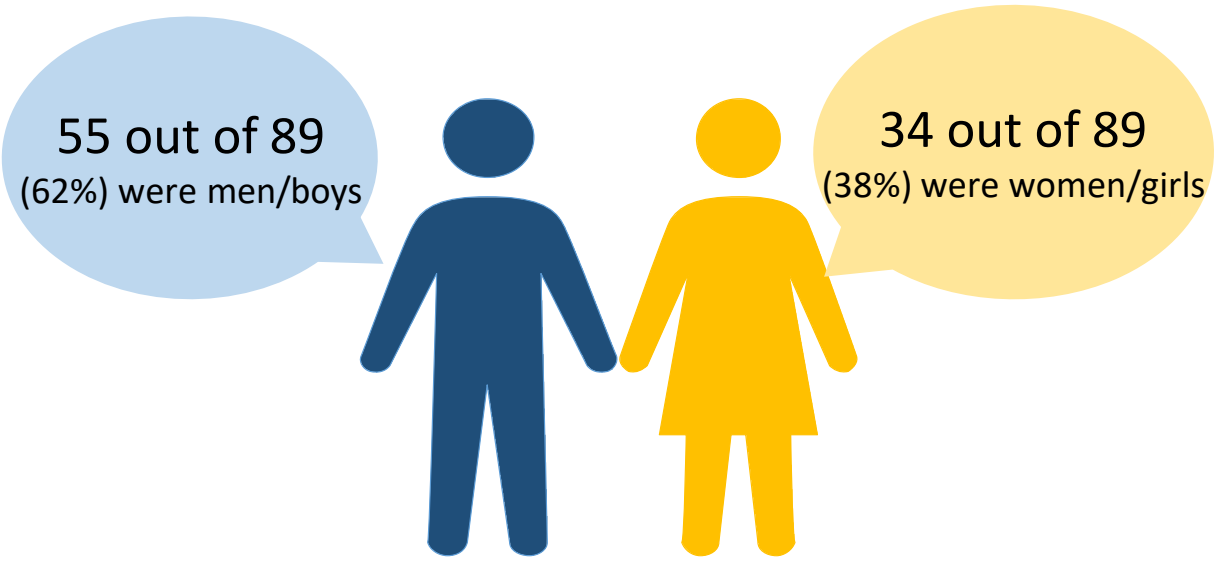
A total of 89 participants were treated with MAR-CUTIS or Dermabond Advanced in this trial.

How old were the participants?

The average age of participants was 48 years. The youngest participant was 2 years old and the oldest participant was 85 years old.



Were the participants' men/boys or women/girls?



Which participants were able to take part in the trial?

Participants were only able to take part in the trial if they met certain criteria. This was important to make sure that it was safe for each participant to take part in the trial, that the results of the trial were valid, and that the laws and regulations were followed.

People could take part in this trial if they:

- ☑ were at least 2 years of age.
- ☑ weighed at least 10 kilos.
- ☑ had surgery or an injury causing open wounds or cuts.
- ☑ required closure of deep wounds and cuts on face or limbs.
- ☑ gave written consent for self; children were assented by parents or legal guardian.

What happened during this trial?

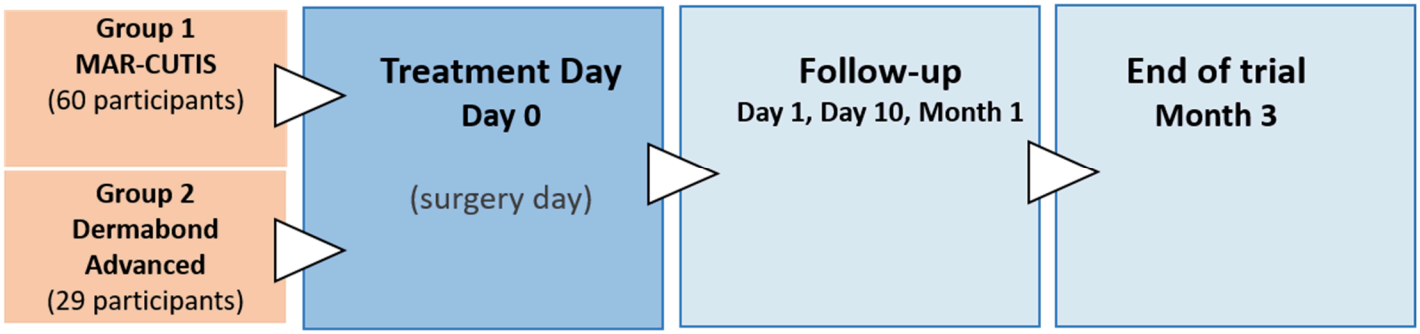
This was a pivotal trial that compared the skin glue devices MAR-CUTIS and Dermabond Advanced. Pivotal device trials are done for researchers to confirm the effects of the trial device and its safety.

The trial had 3 periods: screening, treatment and follow-up.

This trial was "open-label". This means that both the researchers and the participants knew which skin glue device was used on their wound.

Researchers randomly assigned participants to one of the 2 device groups using a computer system. This process is called randomisation. It means that each participant could be assigned to either device group and it helps to make sure the groups are distributed fairly.

Skin glue was applied to participants' wound on Day 0. Treated wounds were examined by the trial doctor at the trial site at 1 day (Day 1), 10 days (Day 10), 1 month (Month 1) and 3 months (Month 3) after surgery. All participants were given a diary to record information related to their treated wound. Researchers monitored the health of the participants throughout the trial.



What were the overall results of the trial?

Researchers compared the percentage of participants whose wound was not fully closed or had skin edge separation by Day 10 in the MAR-CUTIS group with the Dermabond Advanced group. Although both skin glue devices seemed to work, the initial trial results showed that MAR-CUTIS was not as good as Dermabond Advanced for closing wounds. As the trial ended early, researchers could not confirm the effects of MAR-CUTIS in participants with surgical cuts and wounds.

During this trial, some participants experienced medical problems which the trial doctor thought could be side effects of the glue used on their surgical cuts and wounds or were related to the device used to stick their cuts and wounds.

Number of participants with side effects by treatment group

Serious side effects: Serious side effects are those that may cause death, disability, lasting problems, life-threatening conditions or hospitalisation.

Serious side effects were not reported in this trial.

Non-serious side effects

Number of participants (%) who had non-serious side effects at application site		
	MAR-CUTIS (out of 60 participants)	Dermabond Advanced (out of 29 participants)
Skin edge separation	6 (10%)	1 (3%)
Wound infection	3 (5%)	0 (0%)
Wound complication	1 (2%)	1 (3%)
Skin edge separation in belly area	0 (0%)	1 (3%)
Skin allergy	0 (0%)	1 (3%)
Wound infection caused by bacteria	0 (0%)	1 (3%)
Wound with dead skin	0 (0%)	1 (3%)

Side effects related to the device

Number of participants (%) who had expected side effects		
	MAR-CUTIS (out of 60 participants)	Dermabond Advanced (out of 29 participants)
Skin edge separation	3 (5%)	0 (0%)
Wound complication	0 (0%)	1 (3%)

Number of participants (%) who had unexpected side effects		
	MAR-CUTIS (out of 60 participants)	Dermabond Advanced (out of 29 participants)
Internal or external bleeding	0 (0%)	1 (3%)

How was this trial useful for patients and researchers?

Because the trial ended early, researchers could not confirm the effects of MAR-CUTIS on the closure of surgical cuts and wounds.

Findings from this trial may be used in other trials with MAR-CUTIS. There are no ongoing trials for MAR-CUTIS.

The results described in this report are for one trial. The findings of other trials might be different. How MAR-CUTIS works and how safe it is to use must not be judged on the results of one clinical trial alone.

If you have questions, please contact your trial doctor.

Where can I learn more about this trial?

You can find more information about this trial on the following website:

www.clinicaltrials.gov

Use the NCT identifier NCT03688880 in the search field.

Full trial name: A randomised, open-label, multi-centre, controlled clinical study to compare MAR-CUTIS with Dermabond Advanced in closure of surgical incisions and lacerations ≤15 cm

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