+ Volunter trial (VT)
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What is a volunteer trial?

Research studies in which researchers assign participants to get one or more interventions (such as a drug, behavior, or medical device) to test what happens in people.[1]

For more information on types of clinical research **CLICK HERE**

Performance of ALLEVYN◊ COMPLETE CARE Foam Dressing in a volunteer trial: comparison with Mepilex™ Border Flex[2]

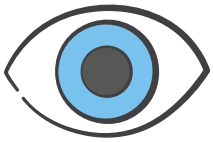
Topline outcomes

73% of **ALLEVYN◊ COMPLETE CARE Foam Dressings** had acceptable dressing presence with 7 days of wear compared to 65% of **Mepilex™ Border Flex/Comfort dressings***[2]

95% of **ALLEVYN COMPLETE CARE Foam Dressings** stayed/remained in place compared to 91% of **Mepilex™ Border Flex dressings***[2]

ComfortSTAY◊ soft silicone adhesive technology had a low incidence of skin irritation*[2]

95% of volunteers found **ALLEVYN COMPLETE CARE Foam Dressings** comfortable compared to 89% for **Mepilex™ Border Flex dressings***[2]



Method

- 120 randomised, healthy participants were recruited in this study.
- Study was conducted at a single, Germany-based site with participants attending 5 site visits.
- Dressings were worn by participants for up to 7 days on intact skin.

Study aims

The study aimed to discover how effectively **ALLEVYN COMPLETE CARE Dressings** stay in place, as well as other dressing performances and safety factors, when compared to two corresponding marketed dressings with a similar intended use profile and shape.

Comparator

- **ALLEVYN COMPLETE CARE Dressing** vs **Mepilex™ Border Flex Dressing** on intact skin on thighs and shins.
- The main aim of the study was to assess **ALLEVYN COMPLETE CARE Dressing's** ability to stay in place for 7 days, compared to established marketed dressings.

What was the inclusion criteria for volunteer to take part?

1. Participant is capable of providing informed consent.
2. Participant is willing and able to make all required study visits.
3. Aged 18-70 years at the time of signing the informed consent.*
4. Participant must be in good health, as determined by the Investigator, based on medical evaluation, including medical history and skin application site assessment (healthy intact skin at or near any of the dressing application sites).
5. Participant is willing not to use cosmetic or medicinal lotions, creams, ointments and anything else which may interfere with dressing adhesion at dressing application sites for the duration of the study from 24 hours before dressing application on Day 0.
6. Participant is willing to have excess hair removed from the dressing application sites.
7. Participant is willing to avoid immersing the dressings in water (no swimming or bathing) for the duration of the study, however, showering was permitted.

For more information on the study **CLICK HERE**

Study measures

Outcome measure	Measure description	Time frame
Primary endpoints		
Acceptable dressing presence at Day 7	Yes/no assessment, with a "yes" response defined as the dressing is in place with no border lift reaching the pad and no pad exposure.	Day 7
Secondary endpoints		
Acceptable dressing presence at Day 1 and Day 3	Yes/no assessment, with a "yes" response defined as the dressing is in place with no border lift reaching the pad and no pad exposure.	Day 1 and 3
Presence of dressing	Response to the question "Is dressing in place?" Yes No	Day 1, Day 3 and Day 7
Pad integrity	Changes to the integrity of the dressing pad (e.g., bunching, folding, ridges) assessed by one of the following percentage categories: 0% (no change) 1–25% 26–50% 51–75% 76–100% Dressing missing	
Pad lift	Lift of the dressing pad assessed to determine the extent of the pad area lifted and no longer adhered to the participant's skin by one of the following percentage categories: 0% (no lift) 1–25% 26–50% 51–75% 76–100% Dressing missing	
Border lift	Lift of the dressing border assessed to determine the extent of the border area lifted and no longer adhered to the participant's skin by one of the following percentage categories: 0% (no lift) 1–25% 26–50% 51–75% 76–100% Dressing missing	
Dressing comfort	Dressing comfort assessed by the participant's answer to the question "Was the dressing comfortable during wear?" from one of the following responses: Yes No Dressing missing	

NOTE: Acceptable dressing presence is defined as the dressing is in place with no border lift reaching the pad and no pad exposure at day 7.

*As demonstrated in a volunteer trial. 120 volunteers wore both dressings on intact skin for up to 7 days on their thighs or shins. †At least 10% of participants are aged >55 years.

References: 1. ClinicalTrials.gov. About ClinicalTrials.gov. Available at: https://www.clinicaltrials.gov/about-site/about-ctg#q3. Accessed August 6, 2025. **2.** Smith+Nephew 2025. Topline results from ALLEVYN® COMPLETE CARE Foam Dressing volunteer trial (HVS2313) on thighs and shins. Internal report CSD.AWM.25.032.

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