Bioequivalence Assessment of Topical Smartech 2% Diclofenac Sodium Solution Compared to a Reference Product When Applied to the Knees of Healthy Male and Female Participants

ACTRN12624000341527

Status	RECRUITING
Phase	Phase 1
Sponsor	Smartech Topical AU Pty Ltd
Enrollment	90 participants

Plain Language Summary

Diclofenac is a well-known anti-inflammatory pain reliever (NSAID) that can be applied as a gel or solution directly to sore joints or muscles, avoiding many of the side effects of oral tablets. This study is testing whether a new formulation — Smartech Formulation 2, a 2% diclofenac sodium topical solution — has the same level of absorption into the bloodstream as the existing reference product Pennsaid 2%.

This is a bioequivalence study, conducted in healthy adults, applying the solutions to both knees twice daily for 7.5 days. Blood samples are taken at regular intervals to measure the medication levels. If the new formulation is shown to be bioequivalent, it means it can be used interchangeably with the existing product.

You may be eligible if you are 18-55 years old, in good health, are a non-smoker, and have no significant medical history. You must be willing to avoid sunlight on your knees and refrain from moisturiser, exercise, and caffeine during the study periods. People with known allergies to diclofenac or NSAIDs, significant heart, kidney, or liver problems, or who are pregnant are not eligible. This study is an important step in making an affordable anti-inflammatory option available to more patients.

Key Eligibility Criteria

Inclusion (27)

- Have signed and dated a Human Research Ethics Committee (HREC)-approved informed consent.
- Are between 18 – 55 years of age (inclusive) at the time of informed consent signature.
- Have a body mass index (BMI) between 19 to 32 kg per m2 at Screening and at CRU admission on Day -1 for the first Study Period, as applicable.
- Are nonsmokers (including tobacco, e-cigarettes or equivalent) for at least 1 month prior to planned first study drug administration, and are willing to not smoke while confined at the CRU.
- Are medically healthy without clinically significant (in the opinion of the Investigator (or qualified designee) abnormalities at Screening and at CRU admission on Day -1 for the first Study Period, as applicable, including:

... and 22 more (see full listing online)

Exclusion (28)

- Participants are not eligible for participation in the study if they meet any of the following criteria:
- Have a known hypersensitivity to diclofenac sodium, salicylates or other NSAIDs.
- Have a history of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.
- Have risk factors for cardiovascular thrombotic events; known cardiovascular disease or risk factors for cardiovascular disease.
- Have had a coronary artery bypass graft surgery within the past 12 months.

... and 23 more (see full listing online)

Locations (1 total)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000341527

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