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A study to see if TAR-0520 gel can help prevent nerve damage caused by certain cancer treatments

Submission date
28/07/2025

Recruitment status
No longer recruiting

Registration date
31/07/2025

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common type of cancer worldwide. Treatments often include drugs called taxanes, such as docetaxel and paclitaxel. While these drugs are effective, they can cause a condition called chemotherapy-induced peripheral neuropathy (CIPN), which affects the nerves and leads to pain, numbness, and sometimes difficulty with movement. Nail problems like onycholysis (where nails separate from the nail bed) are also common. This study is testing a new gel called TAR-0520, developed by Tarian Pharma, to see if it can help prevent these side effects when applied to the hands.

Who can participate?
The study is open to cancer patients who are receiving treatments known to cause skin and nerve-related side effects, such as EGFR inhibitors and taxanes.

What does the study involve?
Participants will receive one of the following chemotherapy treatments:
-Docetaxel every 3 weeks for 4 cycles
-Docetaxel every 3 weeks for 6 cycles
-Paclitaxel every week for 12 cycles
During each cycle, participants will apply TAR-0520 gel to both hands, including the fingers, twice a day for three days. The first dose is applied two hours before chemotherapy. This routine is repeated with each new cycle.

What are the possible benefits and risks of participating?
The gel may help prevent painful nerve symptoms and nail problems, which could allow patients to continue their treatment without interruption and improve their overall quality of life. Previous studies have shown only mild skin irritation as a side effect, and the gel does not enter the bloodstream in significant amounts.

Where is the study run from?
The study is being conducted at Royal Green Hospital in Moka, Mauritius.

When is the study starting and how long is it expected to run for?
August 2024 to July 2026

Who is funding the study?
Tarian Pharma, France.

Who is the main contact?
Dr Vikramsingh Kimcurran, v.kolanthan@cidp-cro.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
TAR-015

Study information

Scientific Title
A phase 2 exploratory study to evaluate the efficacy of TAR-0520 gel in the prevention of peripheral-neuropathy induced by taxanes

Study objectives
This study plans to explore the preventative effect of TAR-0520 Gel on CIPN induced by taxanes in cancer patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 18/06/2025, Clinical Research Regulatory Council (CRRC) (Level 2, Nexsky Building, Ebene, Ebene, 72201, Mauritius; +230 59439503; crrc@govmu.org), ref: 2425CMPH052

Primary study design

Interventional

Study design
Phase II monocentric open pilot efficacy study

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Prevention of localised cutaneous side effects induced by chemotherapy

Interventions
All participants will receive TAR-0520 gel alongside their standard chemotherapy regimen.
Treatment Details
Chemotherapy Regimens:
Docetaxel every 3 weeks for 4 cycles
Docetaxel every 3 weeks for 6 cycles
Paclitaxel weekly for 12 cycles
Investigational Product: TAR-0520 Gel
Administration: Topically applied to both hands including fingers
Dose and Schedule:
Twice daily for 3 consecutive days per chemotherapy cycle
Application starts on the day of taxane infusion
First application is 2 hours before taxane administration
Followed by twice-daily application for the next 2 days
Treatment is paused until the next cycle, where the same regimen is repeated.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
TAR-0520 Gel

Primary outcome(s)
Peripheral neuropathy symptoms measured using the modified Chemotherapy-Induced Peripheral Neuropathy (CIPN) Patient-Reported Outcome (PRO) questionnaire (hands and feet subscales) at Day 1 (Week 1), Week 4, Week 7, Week 10, Week 13, Week 16, and at the follow-up visit 4 weeks after the last chemotherapy cycle

Key secondary outcome(s)
1. Adverse events (AEs) collected through patient interviews and review of medical records at Day 1 (Week 1), Week 4, Week 7, Week 10, Week 13, Week 16, and at the follow-up visit 4 weeks after the last chemotherapy cycle
2. Physical examination (covering skin, lungs, abdomen, neurological function, musculoskeletal system, lymph nodes, cardiovascular system) conducted by the investigator at screening (Day -15), Day 1 (Week 1), and at the end of the study or early termination visit

3. Vital signs (systolic and diastolic blood pressure and pulse rate, measured after 5 minutes in sitting position) at screening visit, Day 1 (Week 1), Week 4, Week 7, Week 10, Week 13, Week 16, and at the follow-up visit 4 weeks after the last chemotherapy cycle

Completion date
30/07/2026

Eligibility

Key inclusion criteria
1. Adult patients
2. Cancer patients planned to be treated with taxane perfusions (docetaxel or paclitaxel) as part of their chemotherapy protocol. Any type of cancer requiring taxane treatment (breast, ovarian, prostate, urinary bladder, pancreatic or lung cancer) can be included. Taxane treatment can be the first or second line of treatment.
3. Patients, with or without metastasis, whose condition is considered stable and compatible with the participation to a clinical trial
4. Patients understand and agree to comply with the requirements of the clinical trial protocol.
5. Female patients of childbearing potential agree to use a highly effective method of contraception throughout the study. Highly effective method of contraception can be:
- combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal)
- progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable)
- intrauterine device (IUD)
- intrauterine hormone-releasing system (IUS)
- bilateral tubal occlusion
- vasectomized partner
- sexual abstinence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients already treated with taxanes or other chemotherapies known to induce neuropathies in the past year
2. Patients with diagnosed peripheral neuropathy whatever its cause (Diabetes, Alcoholism, HIV, Peripheral vascular disease, Vitamin B deficiencies). Pre-diabetic patients without neuropathy

can be included
3. Patients with concomitant therapies known to induce neuropathies
4. Patients treated for neuropathic pain
5. Patients who will not be able to follow the protocol for physical or psychological reasons
6. Patients currently receiving monoamine oxidase (MAO) inhibitors therapy or patients on antidepressants which affect noradrenergic transmission e.g. tricyclic antidepressants and mianserin (as mentioned in the current topical brimonidine labeling of approved products).
7. Female who is pregnant or lactating
8. Female who intends to conceive a child during the clinical trial

Date of first enrolment
01/09/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Mauritius

Study participating centre
Royal Green Hospital
Reduit Triangle
Moka
Mauritius
80801

Sponsor information

Organisation
TARIAN PHARMA

Funder(s)

Funder type
Industry

Funder Name
Tarian Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date