

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

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| <b>Submission date</b><br>28/07/2025   | <b>Recruitment status</b><br>No longer recruiting                | <input checked="" type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>31/07/2025 | <b>Overall study status</b><br>Ongoing                           | <input type="checkbox"/> Protocol                               |
| <b>Last Edited</b><br>29/07/2025       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> Statistical analysis plan              |
|  |  | <input type="checkbox"/> Results                                |
|  |  | <input type="checkbox"/> Individual participant data            |
|  |  | <input checked="" type="checkbox"/> 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

### Contact name

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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

### Study design

Phase II monocentric open pilot efficacy study

### **Primary study design**

Interventional

### **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