

# Evaluation of Acetyl-L-Carnitine (ST 200) to reduce intensity of taxanes- or platinum-induced sensory neuropathy

<b>Submission date</b> 24/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/08/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Massimo Ildebrando

### Contact details

Via Pontina km 30,400  
Pomezia (Rome)  
Italy  
00040

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ST200-DM-04-005

## Study information

## Scientific Title

### Study objectives

The clinical hypothesis to be verified is 20% response rate in the placebo group versus 40% response rate in the Acetyl-L-Carnitine group where a responder is defined as a patient having obtained a decrease of at least one grade in the NCI-CTC sensory score at treatment end as compared to baseline.

Please note that this record was updated on 05/11/2007. Changes were made to the countries of recruitment, the inclusion criteria, and the anticipated end date. The previous end date for this trial was 31/12/2006.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the following ethics committees:

1. Università degli Studi G. d'Annunzio on the 21st July 2005
2. Direzione Sanitaria del P.O.S. Gerardo on the 16th September 2005
3. Presidio Arcispedale Santa Maria Nuova on the 9th September 2005
4. dell'A.U.S.L. Roma H on the 19th September 2005
5. Servizio di Farmacia on the 26th September 2005
6. Segreteria del Comitato Etico on the 15th September 2005
7. Comitato Etico per la Sperimentazione clinica dei medicinali on the 6th February 2006
8. Commissione Etico-Scientifica - ASL Rimini on the 12th October 2005
9. Istituto Nazionale per lo Studio e la Cura dei Tumori on the 20th February 2006

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Taxanes- or platinum-induced neuropathy

### Interventions

Placebo versus Acetyl-L-Carnitine.

**Efficacy:**

Neuropathy will be assessed by a neurologist at each study visit using: sensory and motor items of National Cancer Institute - Common Toxicity Criteria (NCI-CTC) version 3.0; vibration examination; total neuropathy score (TNS); clinical neurological evaluation; electroneurography (ENG).

**Safety:**

Physical examinations, electrocardiograms (ECGs), vital signs, laboratory tests, adverse events and concomitant medications will be considered for the safety and tolerability evaluation.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Acetyl-L-Carnitine (ST 200)

**Primary outcome measure**

The sensory item of NCI-CTC version 3.0 dated December 12th 2003 will be the primary endpoint. In accordance with the primary objective of the study, the proportion of responder patients measured at treatment end (i.e. visit 2) will be the primary endpoint.

**Secondary outcome measures**

1. Motor item of NCI-CTC version 3.0
2. Ulnar, sural and common peroneal nerve conduction velocity (NCV)
3. Symptoms/signs of peripheral damage
4. Vibration perception threshold
5. Total neuropathy score (TNS)
6. Plasma NGF level

All the variables will be descriptively analysed by treatment and visit (mean, median, standard deviation, minimum and maximum for continuous variables, frequency distribution for categorical variables). Efficacy analysis will be applied in all populations. Results from the ITT population will be considered the primary ones.

**Overall study start date**

01/07/2005

**Completion date**

01/06/2009

**Eligibility****Key inclusion criteria**

Current inclusion criteria as of 05/11/2007:

Patients (male and female aged 18 or more years and Karnofsky greater than 60) previously treated with taxanes- or platinum-based chemotherapy and presenting sensory neuropathy, will be randomised to receive placebo or Acetyl-L-Carnitine.

Previous inclusion criteria:

Patients (male and female age between 18 and 70 years and Karnofsky >60) previously treated with taxanes- or platinum-based chemotherapy and presenting sensory neuropathy, will be randomised to receive placebo or Acetyl-L-Carnitine.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

172

**Key exclusion criteria**

1. Pre-existing neuropathies of different origin than those considered in this trial
2. Diabetes mellitus, insulin-dependent
3. Symptomatic brain metastases
4. Leptomeningeal involvement
5. Significant infective illness or active inflamed focus
6. Concomitant therapy with other neuroprotective agents
7. Any previous use of neuro-protectant drugs if performed from the last chemotherapy administration, onwards
8. Any neurotoxic chemotherapy since one month prior to baseline
9. Predictable lack of patient's co-operation
10. Pregnancy, nursing, or women of childbearing potential not using an effective method of birth control
11. Previous treatment with platinum for those patients who enter the study due to taxanes-induced sensory neuropathy
12. Previous treatment with taxanes for those patients who enter the study due to platinum-induced sensory neuropathy

**Date of first enrolment**

01/07/2005

**Date of final enrolment**

01/06/2009

**Locations**

**Countries of recruitment**

Belgium

France

Italy

**Study participating centre**

Via Pontina km 30,400

Pomezia (Rome)

Italy

00040

## Sponsor information

**Organisation**

Sigma-Tau (Italy)

**Sponsor details**

Industrie Farmaceutiche Riunite, SpA

Via Pontina km 30,400

Rome

Italy

00040

**Sponsor type**

Industry

**ROR**

<https://ror.org/03bxtpd68>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Sigma-Tau i.f.r. S.p.A. (Italy) (Protocol ref: ST200-DM-04-005)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration