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

Submission date	Recruitment status	[ ] Prospectively registered
24/05/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/08/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2008	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 medicinalion the 6th February 2006
8. Commessione 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 ilness or active inflamed focus
6. Concomitant therapy with other neuroprotective agents
7. Any previous use of neuro-protectant drugs if performed from the last chemoteraphy 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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration