Fatigue after prophylactic cranial irradiation in small cell lung cancer patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26234

Source
NTR

Brief title
N/A

Health condition

fatigue, small cell lung cancer (SCLC), PCI
vermoeidheid, kleincellig longcarcinoom, profylactische schedelbestraling

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: MUMC+

Intervention

Outcome measures

Primary outcome

Onset and level of fatigue after PCI measured by VAS

Secondary outcome

Onset and level of fatigue after PCI measured by additional questionnaire: MVI-20

Changes in quality of life (Qol) after PCI: EORTC c30 and EuroQol-5D

Study description

Background summary

Cancer related fatigue (CRF) is a common problem in oncological patients. 50-90% of oncological patients experience fatigue, the highest percentage is found in patients treated with chemo- and/or radiotherapy. CRF is one of the most important complaints related to cancer and its treatment. It is also a strong and independent predictor of quality of life (QoL) and patient satisfaction. After PCI, SCLC patients experience significantly more fatigue than patients who have not had PCI. Duration of fatigue after PCI is approximately 3 months, but no data exist regarding onset and peak of fatigue complaints after PCI. To plan starting time and duration of fatigue-modifying treatment, we want to evaluate in this study onset, peak and duration of fatigue after PCI (only in SCLC stage I-III) by VAS and other questionnaires

Study objective

Fatigue will be at its worst 2 to 3 weeks after prophylactic cranial irradiation (PCI)

Study design

first questionnaires to be completed in week before PCI, the first month after PCI the questionnaires have to be completed every week, the next two months the questionnaires have to be completed every two weeks

Intervention

questionnaires:

regarding fatigue: VAS and MVI-20
regarding quality of life: EORTCc30 and EuroQol 5D

Contacts

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Eligibility criteria

Inclusion criteria

-Age >=18 years

-SCLC, pathology proven

-Completed initial treatment, with at least stable disease

-WHO PS ¡Ü 2

-Ability to understand written questionnaires

-Written informed consent

Exclusion criteria

- clinically relevant anemia (defined as Hb < 6 mmol/l)

- chronic renal failure (defined as MDRD-eGFR < 45 ml/min/1.73m)

- liver biochemistry abnormalities (defined as more than two times upper limit of normal)

- major psychiatric illness requiring intervention in secondary care

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	7
Type:	Actual

Ethics review

Positive opinion

Date:	21-10-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4067
NTR-old	NTR4218
Other	: METC 13-4-074
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A