TEACH survey, a prospective survey on the incidence of venous thromboembolic events during chemotherapy for solid tumors

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To prospectively assess the incidence of venous thromboembolic events (VTE),i.e. deep vein thrombosis and/or pulmonary embolism, in patients receivingchemotherapy for selected solid tumors.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON30286

Source
ToetsingOnline

Brief title
TEACH survey (Thrombo-Embolism And Chemotherapy)

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Embolism and thrombosis

Synonym
cancer, malign tumors

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research and Treatment of Cancer
Source(s) of monetary or material Support: EORTC,Sanofi-aventis

Intervention

Keyword: Chemotherapy, Neoplasm, Venous thromboembolism

Outcome measures

Primary outcome

The primary endpoint is a composite of any of the following outcomes:

* asymptomatic proximal deep vein thrombosis of the lower limbs

* confirmed symptomatic deep vein thrombosis of the lower limbs

* confirmed pulmonary embolism

Secondary outcome

n.a.

Study description

Background summary

Venous thromboembolism (VTE) comprises both deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE occurs more frequently in patients with cancer compared to patients with other diseases. In a large population based study, the overall risk of VTE was increased 7-fold in cancer patients versus patients without a malignancy. The incidence of VTE seems to increase in patients treated with chemotherapy. Studies in patients at high risk for VTE, even with the use of thromboprophylaxis, showed that most of the VTEs were asymptomatic (approximately 2-3% symptomatic versus 10-40% asymptomatic). So clinical judgment underscores the rate of VTE in high-risk patient groups. This accounts for cancer patients as well. The fatality rate in cancer patients is high: of every seven patients with cancer who die in hospital, one dies of pulmonary embolism. The majority of these patients (approximately 60%) has localized cancer or limited metastatic disease and would have survived for longer in absence of VTE.
Most studies on the risk of venous thromboembolism following chemotherapy have

been retrospective analyses. Such studies are more likely to suffer from methodological flaws. Data from scarce prospective observational studies showes that the incidence of VTE in chemotherapy treated patients is considerable (between 2-22%). No trial has been performed investigating VTE in a standardized way, so the figures mentioned concerning only symptomatic VTE. Studies in surgical patients showed a benefit for prophylactical treatment with anticoagulant therapy in the prevention of VTE.

Study objective

To prospectively assess the incidence of venous thromboembolic events (VTE), i.e. deep vein thrombosis and/or pulmonary embolism, in patients receiving chemotherapy for selected solid tumors.

Study design

After being registered, patients will be followed prospectively for up to 3months from the start of the present chemotherapy regimen in the survey. Chemotherapy should start within 1 week after registration.
Compression ultrasounds of the lower limbs will be done:
* at baseline: after registration before the start of chemotherapy
* at end of observation: systematically after three months or earlier if deep vein thrombosis is suspected or if anticoagulant therapy for more than 5 days for curative treatment or thrombo-prophylaxis is initiated for any reason

Study burden and risks

The burden for the patients consists of 2 ultrasounds of the lower extremities. The duration of the ultrasound is approximately 10 minutes (x2= 20 minutes). The ultrasound is non-invasive, and painless. The risk for complications is neglectible.

Contacts

Public
European Organisation for Research and Treatment of Cancer

Avenue E. Mounierlaan 83/11
1200 Brussel
Belgie
Scientific
European Organisation for Research and Treatment of Cancer

Avenue E. Mounierlaan 83/11
1200 Brussel
Belgie

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Patients who are scheduled to receive chemotherapy of >= 3 months duration for cytologically or histologically proven:
o breast cancer (metastatic)
o colorectal cancer ((neo-) adjuvant or palliative chemotherapy)
o gastric cancer ((neo-) adjuvant or palliative chemotherapy)
o lung cancer ((neo-) adjuvant or palliative chemotherapy)
o ovarian cancer ((neo-) adjuvant or palliative chemotherapy)
o pancreatic cancer ((neo-) adjuvant or palliative chemotherapy)
o prostate cancer (hormone-refractory)
- Life expectancy of more than 3 months
- Informed consent given by patient for data collection and ultrasonography

Exclusion criteria

- No chemotherapy within 6 weeks before the start of the observation period
- No major surgery including surgery for cancer within 4 weeks before the start of the observation period
Note: minor surgery, e.g. implant of a port-a-cath, within these 4 weeks is allowed.
- No major surgery including surgery for cancer planned during the

observation period
Note: Radiotherapy before or during the observation period is allowed.
- Patients with a history of DVT or PE can be included if treatment and secondary prevention of the last episode was completed prior to survey entry.
- No concurrent or scheduled use of thrombo-prophylaxis or any anticoagulant therapy such as parenteral anticoagulants (heparin, low molecular weight heparins or other agents such as fondaparinux, bivalirudin), oral anticoagulants (vitamin K antagonists) or thrombolytic agents

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL14703.048.06