Determining the clinical relevance of the inTeraction between AprepitaNt aNd EtoposiDe; an observational pharmacokinetic study (TANNED-study)

Published: 22-03-2021
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To investigate the influence of aprepitant on the exposure to etoposide in TC patients treated with (B)EP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Testicular and epididymal disorders
Study type	Observational invasive

Summary

ID

NL-OMON50969

Source
ToetsingOnline

Brief title
TANNED

Condition

- Testicular and epididymal disorders

Synonym
testicular cancer, testicular germ cell tumor

Research involving
Human

Sponsors and support

Primary sponsor: Afdeling Apotheek
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aprepitant, etoposide, interaction, pharmacokinetic

Outcome measures

Primary outcome

the exposure (AUC0-24 hr) to etoposide in TC patients treated with (B)EP.

Secondary outcome

Not applicable

Study description

Background summary

In metastatic testicular cancer, first-line chemotherapy consists of bleomycin, etoposide and cisplatin (BEP) or etoposide and cisplatin (EP) in case of contraindications for bleomycin.
As a result of the combination with cisplatin, this treatment is classified as highly emetogenic. Depending on the degree of emetogenicity different combinations of antiemetics are prescribed. The effectiveness of aprepitant in combination with ondansetron and dexamethasone to prevent or reduce nausea was demonstrated in several studies where aprepitant was seen to be particularly effective in reducing late onset nausea.
In pharmacokinetic studies, aprepitant was shown to be a moderate inhibitor of CYP3A4 activity during the first days after administration and a moderate inducer of CYP3A4 after cessation of therapy. Etoposide is metabolized by CYP3A4, which may also make etoposide susceptible to interact with aprepitant.
The purpose of this study is to determine the clinical relevance of the interaction between etoposide and aprepitant in patients with TC treated with etoposide partly in combination with aprepitant. The results of this study can contribute to optimize the antiemetic treatment for patients treated with high emetogenic etoposide combination therapy.

Study objective

To investigate the influence of aprepitant on the exposure to etoposide in TC patients treated with (B)EP.

Study design

single centre, prospective, open-label, observational pharmacokinetic study

Study burden and risks

Patients who participate in the study will receive standard treatment conform local protocol. Therefore the risk for participation in this study is regarded negligible. Collection of blood do not put patients at risk or interfere with standard treatment.

Contacts

Public
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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria:
• Patients with TC who will start or already started treatment with (B)EP
• Age of at least 18 years
• Patients from whom it is possible to collect blood samples
• Patients who are able and willing to give written informed consent prior to screening

Exclusion criteria

• Patients who are co-treated with drugs that could interfere with the metabolism of etoposide (including drugs classified as a weak, moderate or strong CYP3A4 inhibitor OR weak, moderate and strong inducers of CYP3A4 according to the table based on the Flockhart table).

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2021
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	emend
Generic name:	aprepitant
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Etoposide
Generic name:	etoposide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2021-000342-17-NL
CCMO	NL76372.091.21