

ONDERZOEK NAAR EFFECT VAN BEVACIZUMAB BEHANDELING BIJ MELANOMEN M.B.V. MOLECULAIRE BEELDVORMING.

Gepubliceerd: 09-08-2009 Laatste bijgewerkt: 13-12-2022

To identify biological effects of bevacizumab and to visualize distribution kinetics of ¹¹¹In-bevacizumab with gamma-camera imaging.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21967

Bron

NTR

Verkorte titel

N/A

Aandoening

melanoma, imaging, VEGF, bevacizumab

Ondersteuning

Primaire sponsor: UMCG

Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1 - ONDERZOEK NAAR EFFECT VAN BEVACIZUMAB BEHANDELING BIJ MELANOMEN M.B.V. MOLECULAIRE ...
5-05-2025

To identify biological effects of bevacizumab therapy and to visualize distribution kinetics and uptake of ¹¹¹In-bevacizumab in the micro-environment of the tumor with gamma-camera imaging.

Toelichting onderzoek

Achtergrond van het onderzoek

Observational study evaluating the anti-angiogenic and apoptotic response of bevacizumab in patients with surgically resectable melanoma.

Patients with surgically resectable melanoma, who are planned for surgery will be treated neo-adjuvant with bevacizumab therapy. The anti-angiogenic and apoptotic response will be evaluated by measuring hematological and histological parameters. The distribution kinetics of ¹¹¹In-bevacizumab will be visualized by gamma-camera imaging. The patients will receive two injections of ¹¹¹In-bevacizumab and four gamma-camera scans. The first 2 scans will serve as a baseline. After the second scans it will be possible to compare imaging data before and after treatment and hereby evaluate tumor response.

Doel van het onderzoek

To identify biological effects of bevacizumab and to visualize distribution kinetics of ¹¹¹In-bevacizumab with gamma-camera imaging.

Onderzoeksopzet

VEGF-SPECT imaging at baseline and 2 weeks following bevacizumab treatment prior to surgical resection.

Onderzoeksproduct en/of interventie

1. Administration of 7.5 mg/kg bevacizumab;
2. VEGF-SPECT imaging.

Contactpersonen

Publiek

[default]

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Surgically resectable melanoma, stage III or IV;
2. WHO performance status 0-2;
3. Age >18 years;
4. Minimum required laboratory data:
 - A. Hematology: Leucocytes 4,0-10,0x10⁹/l;
 - B. Biochemistry: bilirubin < 1.5 x upper normal limit;
 - C. Serum creatinine within normal limits INR < 1.5.
5. Before patient registration/randomization, written informed consent must be given according to national and local regulations;
6. Able to comply with the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior chemotherapy or biological therapy for metastatic disease;
2. Prior radiotherapy on the involved area;
3. Major surgery within 28 days before the initiation of the study;
4. Clinically significant cardiovascular disease;

5. Pregnant or lactating women. Documentation of a negative pregnancy test must be available for pre-menopausal women with intact reproductive organs and for women less than two years after menopause;
6. CNS metastases (CT-Scan not mandatory);
7. Treatment with any investigational drug within 30 days before the start of the study;
8. Prior allergic reaction to immunoglobulins or immunoglobulin allergy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	11-01-2007
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	09-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1831
NTR-old	NTR1941
Ander register	:

Resultaten

Samenvatting resultaten

N/A