Effect van een zoutbeperkt dieet op de bloeddrukstijging die door behandeling met sunitinib of regorafenib kan ontstaan
Subtitel:
Preventie van bijwerkingen vanVEGF-remmers door zoutbeperking (SUN-SALT studie)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24531

Source
NTR

Brief title
SUN-SALT

Health condition

Hypertension; VEGF inhibitor-induced toxicity; renal carcinoma; thyroid carcinoma; hepatocellular carcinoma; gastrointestinal stroma cell tumor

Sponsors and support

Primary sponsor: ErasmusMC University Medical Center Rotterdam
Source(s) of monetary or material Support: Foundation "De Merel"

Intervention

Outcome measures

Primary outcome

mean difference in blood pressure rise between the treatment cycle with and the treatment cycle without salt restriction.

Secondary outcome

effects of salt restriction on rise in endothelin-1, proteinuria as marker for nephropathy and pharmacokinetics of sunitinib and regorafenib; if an effect on blood pressure is shown, further analyses of effects on renal transporter proteins will be performed to explain the mechanism of salt sensitivity.

Study description

Background summary

Rationale: Growth and metastatic spread of a malignant tumor requires the formation of new blood vessels. Recent therapies target this mechanism by inhibiting vascular endothelial growth factor (VEGF)-signalling. Although this is an effective anticancer treatment, many patients develop cardiovascular side effects such as hypertension and kidney disease, frequently requiring dose reduction and/or early termination of treatment while still effective. Therefore, strategies to prevent VEGF inhibitor-induced toxicity are urgently needed.

In animal studies, VEGF inhibitor-induced hypertension is salt-sensitive. In this study, we want to study salt restriction in cancer patients treated with VEGF inhibitors sunitinib and regorafenib as a strategy to attenuate or prevent VEGF inhibitor-induced toxicity, primarily the rise in blood pressure.

Objective: To prospectively study the effect of salt restriction on the rise in blood pressure in response to anti-cancer treatment with the VEGF inhibitor sunitinib and regorafenib.

Study design: This is a single centre prospective open-label intervention study to compare a treatment cycle using salt restriction with the previous treatment cycle without salt restriction.

Study population: Patients treated with sunitinib or regorafenib according to standard of care, using a standard dosing regimen.

Intervention: A salt restricted diet (<4 grams/day) will be started during the off-treatment

period under guidance of a specialized dietititan. Salt-less bread will be provided. The whole period of salt restriction will take four (regorafenib) or five (sunitinib) weeks.

Main study parameters/endpoints: Primary endpoint: mean difference in blood pressure rise between the treatment cycle with and the treatment cycle without salt restriction.

Secondary endpoints: effects of salt restriction on rise in endothelin-1, proteinuria as marker for nephropathy and pharmacokinetics of sunitinib and regorafenib; if an effect on blood pressure is shown, further analyses of effects on renal transporter proteins will be performed to explain the mechanism of salt sensitivity.

Study objective

Salt restriction is an effective strategy to attenuate or prevent VEGF inhibitor-induced toxicity, primarily the rise in blood pressure.

Study design

The last endpoint is at the end of treatment cycle with regorafenib or sunitinib in which the salt restriction was applied

Intervention

Salt restricted (<4g/day) diet

Contacts

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Eligibility criteria

Inclusion criteria

• Registered indication for sunitinib or regorafenib in the standard treatment regime 4 weeks treatment and 2 weeks off (sunitinib) or 3 weeks on/1 week off (regorafenib).

• Blood pressure well controlled at baseline (<135/85 mmHg day average at 24h ABPM or <140/90 mmHg office)

• Written informant consent

• Age ≥ 18 years

Exclusion criteria

• Not providing informed consent or not capable of giving informed consent

• Using antihypertensive drugs other than a calcium channel blocker at baseline

• Weight loss of 10% or more in the previous six months indicating undernutrition

• Insufficient understanding of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2018
Enrollment:	16

Type:	Anticipated

Ethics review

Positive opinion

Date:	09-10-2018
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	NL7340
NTR-old	NTR7556
Other	NL66666.078.18 : MEC 2018-155

Study results