A phase 2a study on the anti-tumoral effect of cannabis oil (THC 10% / CBD 5%) in untreatable advanced hepatocellular carcinoma patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28248

Source
Nationaal Trial Register

Brief title
CanHep study

Health condition

Hepatocellular carcinoma

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: PPP

Intervention

Outcome measures

Primary outcome

Primary Endpoint:

to study objective response rate (ORR) of cannabis oil (THC10% / CBD5%) in untreatable advanced HCC patients by assessing RECIST (Response Evaluation Criteria In Solid Tumors)and modified-RECIST (mRECIST) criteria 6 months after starting cannabis oil.

Secondary outcome

Secondary Endpoint(s):
a. to study objective response rate of cannabis oil in untreatable advanced HCC patients by assessing
- RECIST22 and mRECIST23 criteria at 3 and 9 months after starting cannabis oil.
- levels of the tumor markers alfa-fetoprotein (AFP) and des-gamma-carboxy-prothrombin (DCP) at 3, 6 and 9 months

b. to study quality of life at baseline, 3, 6 and 9 months using questionnaires EORTC-QLQ C30 and EORTC- QLQ HCC18

c. to compare cannabinoid receptor expression in the tumor (based on histology) between baseline and 6 months after treatment with cannabis oil.

d. to compare immune cell presence in:
- blood at time points baseline, 3, 6 and 9 months after treatment with cannabis oil.
- tumor tissue at time points baseline and 6 months after treatment with cannabis oil

Study description

Background summary

Rationale: Hepatocellular carcinoma (HCC) is the most common primary liver malignancy. It has been recognized as a leading cause of death among patients with cirrhosis, and its incidence is expected to increase in the future. Moreover, HCC can also develop in non-cirrhotic liver. A large proportion of patients presenting with HCC, either cirrottic or non-cirrhotic, are untreatable. For those patients, best supportive care is current practice.
Objective: to explore the anti-tumoral effect of cannabis oil in patients with untreatable advanced hepatocellular carcinoma
Study design: A phase 2 pilot study, in which 20 (10 cirrhotic and 10 non-cirrhotic patients) will be treated with cannabis oil (THC10% / CBD5%).
Study population: patients (>18 yrs) with untreatable advanced HCC (histologically proven) with no other treatment option than best supportive care.
Intervention (if applicable): Cannabis oil (THC10%/CBD 5%) with self-titration scheme.
Main study parameter/endpoint: Objective response rate by assessing RECIST (Response Evaluation Criteria In Solid Tumors) and modified-RECIST (mRECIST) criteria 6 months after start of the treatment.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Many oncological patients use cannabis oil without supervision. Patients who will

participate should visit the hospital three extra times for imaging purposes and outpatient clinic visits, including blood test for liver and kidney function, tumor markers, cannabinoid metabolites and T-cells. Additionally, a second tumor biopsy will be taken. During the titration period and 2 weeks thereafter, patients are not allowed to drive a car.
A possible benefit by anti-tumor effect is the subject of the study. Since the carcinogenenesis of HCC arising from cirrhotic livers may be different when arising from non-cirrhotic livers, the effect of cannabis oil may be different. Therefore, both groups of patients will participate in this study.

Study objective

Cannabis oil (THC10% / CBD5%) appears to have an anti-tumoral effect in untreatable advanced HCC-patients.

Study design

0,3,6 and 9 months

Intervention

Cannabis oil (THC10% / CBD5%)

Contacts

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Eligibility criteria

Inclusion criteria

- Age =>18 yrs
- Histologically proven hepatocellular carcinoma

- MDT-advised best supportive care for untreatable advanced HCC or patients unable to undergo or declining
treatment for advanced HCC.
- Minimal life expectancy of 3 months
- Willing and able to attend follow-up examinations
- Willing to stop driving until 2 weeks after the titration period, if applicable
- Signed informed consent
- Language: Dutch or English

Exclusion criteria

- Mental conditions rendering the subject incapable to understand the nature, scope and consequences of the
trial
- Use of medicinal cannabis for other purposes
- Contra-indications for medicinal cannabis oil:
o Patients who have experienced a myocardial infarction or clinically significant cardiac dysfunction within the
last 12 months or have had a cardiac disorder that, in the opinion of the investigator would have put the
participant at risk of a clinically significant arrhythmia or myocardial infarction.
o Patients with known psychotic disorders
o Female patients who are pregnant or lactating
o Patients (men or women) intending to start a family
o Hypersensitivity to cannabinoids or any of the excipients of the cannabis oil

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-03-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49322
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9079
CCMO	NL68353.042.20
OMON	NL-OMON49322

Study results