# Transarterial embolization of non-bleeding hepatocellular adenomas: a pilot study

Published: 22-08-2018
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To gain insight into the effects of TAE on HCAs and their behavior post-embolisation.

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Hepatobiliary neoplasms malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON47079

**Source**
ToetsingOnline

**Brief title**
Transarterial embolization of non-bleeding hepatocellular adenomas

### Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatic and biliary neoplasms benign

**Synonym**
hepatocellular adenoma, Liver adenoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Benign liver tumours, Hepatocellular adenoma, Interventional radiology, minimal invasive

## Outcome measures

### Primary outcome

Quality of life

tumor size

### Secondary outcome

complications

Malignant transformation

# Study description

### Background summary

Hepatocellular adenoma (HCA) is the most important, albeit uncommon, benign tumour of the liver that mostly occurs in women. A rise in incidence is seen over the last few decades, correlated to the widespread use of oral contraceptives. Other, less common aetiologies include use of anabolic androgens and history of glycogen storage disease. Another cause of the increased incidence is the expended detection by routine ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI) for other reasons. The increasing incidence of obesity, the metabolic syndrome and steatosis might also contribute to this increase, especially to the increased occurrence of HCA in men.

Hepatocellular adenomas are hypervascular lesions comprised of multiple sinusoids of dilated thin-walled capillaries with exclusively arterial blood supply, thereby resulting in a high blood pressure within these tumours, making it susceptible for life threatening bleeding. The risk of spontaneous bleeding, ranging from 20-40% , increases along with the diameter of the tumour, and may require treatment of HCAs even in absence of symptoms. Furthermore, malignant evolvement of this benign process into hepatocellular carcinoma (HCC) may occur in 4.3% of the patients. An established risk factor for this transformation HCC is the size of the HCA, as malignant evolvement is rare in lesions smaller than 5 cm Also a positive *-catenin (exon 3 mutated) status of HCA is associated

with an increased chance of malignant alteration. However, performance of biopsy of an HCA to determine its *-catenin status has not become routine, owing to the risk of sampling error, bleeding and needle-track tumour seeding (the latter two carrying a small risk). Only when the imaging based diagnosis remains uncertain, biopsy will be performed. As a non-invasive diagnostic tool, MRI has become the primary diagnostic tool in identifying HCA subtypes.

Thus far, elective surgical resection has been regarded the gold standard treatment for patients with a HCA, as it provides long-term cure of symptoms, eradicates the possibility of bleeding and malignant evolvement and eliminates the option of leaving a lesion in situ that is misclassified on imaging as being benign. Especially in the group of lesions equal to or larger than 5 cm, resection is advised based on the aforementioned risks of spontaneous bleeding and malignant transformation.

Elective liver resection for non-ruptured benign tumours is still associated with a reported morbidity and mortality of up to 27% and 3%, respectively. incontrast, our review compromising a total of 151 patients undergoing TAE identified no mortality, no need for further surgical management, and effective realisation of haemodynamic stability in the majority of patients receiving TAE. Moreover, our review identified reduction in size on computed tomography (CT) or MRI after embolisation , probably caused by the hypervascular nature of the HCAs with its exclusive arterial blood supply. Finally, transarterial embolisation is hypothesized to be a less invasive treatment for patients with a HCA, of whom the majority is represented by young, otherwise healthy individuals. Cosmetic results are known to play an important role in this group of patients. Regarding the results of previous studies, it appears that TAE is also an effective treatment for non-bleeding HCA , and could therefore also be used in an elective setting to avoid unnecessary laparotomy.

It is this tumour regression in both haemorrhaging and non-haemorrhaging HCAs, its subsequent reduction of the risk of severe haemorrhage and, consequently, probably also malignant transformation, which supports the use of TAE as a treatment for unruptured HCAs * 5 cm. Also, the cosmetic advantages of this minimal invasive technique could benefit the quality of life of this group of young female patients as compared to surgery. However, previous studies were all non-randomised studies and case series, with a limited level of evidence. Moreover, the effect of this procedure on patients` quality of life and the behaviour of these tumours post-procedure in terms of size and remaining vital tumour tissue are not completely understood due to lack of sufficient data. Therefore, prior to investigating this technique in a larger population, a pilot study is needed to gain insight into the effects of TAE on HCAs and their behaviour post-embolisation.

**Study objective**

To gain insight into the effects of TAE on HCAs and their behavior

post-embolisation.

### Study design

Non-randomised pilot study

### Intervention

Transarterial embolisation

### Study burden and risks

The extra hospitalization and the embolisation procedure might be a burden for the patient. The procedure might be painful, as the external iliac artery is punctured. However, adequate painkillers will be administered. The risks of the embolisation procedure are smaller than the risks of the conventional operation. However, a chance exists that patients will undergo both the embolisation procedure and surgery. In this scenario the patient will have the risk of both procedures. However, the embolisation procedure will lower the risk of inter-operative bleeding.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Hepatocellular adenoma(HCA) * 5 cm
- Age at least 18 years
- Withdrawal from oral contraceptives at least 3 months
- Patient fit to undergo liver resection
- Patient understands both the nature and requirements of the study
- BMI between 18-35
- ASA I-III
- Written informed consent
- No suspicion of HCC (normal Alpha foeto protein level)

## Exclusion criteria

- Inability to give written informed consent
- Men (increased risk of malignant transformation)
- HCA presenting with acute bleeding
- History of hepatic malignancy
- Pregnancy
- Claustrophobia (MRI)

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 10 |
| Type: | Anticipated |

## Ethics review

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|---|---|
| Approved WMO Date: | 22-08-2018 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 12-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## 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 | NL60207.018.16 |