PHP in Combination With IPI1/NIVO3 Compared to IPI3/NIVO1 Only in Patients With Uveal Melanoma Liver Metastases

NCT06519266

Status	RECRUITING
Phase	Phase 3
Sponsor	Vastra Gotaland Region
Enrollment	40 participants

Plain Language Summary

This trial is testing a combination of liver-directed treatment (a procedure that delivers chemotherapy directly to the liver) plus low-dose immunotherapy drugs, compared to immunotherapy alone, in people with a rare eye cancer (uveal melanoma) that has spread to the liver.

You may be eligible if...
- You are 18 or older
- You have been diagnosed with uveal melanoma that has spread to the liver (confirmed by biopsy or lab tests)
- The cancer is measurable on a CT scan
- You have not previously been treated for this spread, OR you received tebentafusp and it stopped working
- You are in good general health (able to carry out normal activities)
- You are willing to use effective contraception during and for 5 months after treatment

You may NOT be eligible if...
- The cancer has spread outside the liver (such as to the lungs)
- More than half of your liver is replaced by tumor
- You have serious heart or lung disease that prevents general anesthesia
- You have HIV, active hepatitis B or C
- You have a serious autoimmune disease requiring ongoing treatment
- You are pregnant or breastfeeding
- Your kidneys or liver are not functioning well enough

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (10)

- Patient is e18 years.
- Signed informed consent.
- ECOG performance status of 0 or 1.
- Histologically or cytologically confirmed liver metastasis of uveal melanoma.
- Measurable disease by computed tomography (CT) per RECIST 1.1 criteria with at least one target lesion identified in the liver.

... and 5 more (see full listing online)

Exclusion (18)

- Life expectancy of less than 6 months.
- More than 50% of the liver volume replaced by tumor as measured by CT.
- Extrahepatic disease as measured by CT of thorax and abdomen.

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• History of congestive heart failure, active cardiac conditions, including unstable coronary syndromes (unstable or severe angina, recent myocardial infarction), significant arrhythmias and severe valvular disease that precludes the use of general anesthesia.

• History or evidence of clinically significant pulmonary disease e.g. severe COPD that precludes the use of general anesthesia.

... and 13 more (see full listing online)

Locations (6 total)

Sahlgrenska University Hospital, Gothenburg, Sweden
Linköping University Hospital, Linköping, Sweden
Skåne University Hospital, Lund, Sweden
... and 3 more locations

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