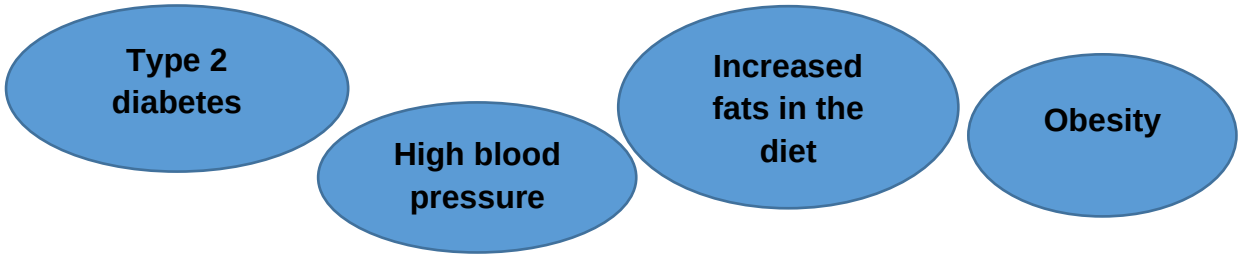
Did you know that people with increased fat in their liver due to Non-alcoholic fatty liver disease (NAFLD) can suffer from cardiovascular related death before suffering from liver related death?

NAFLD is the most common type of liver disease, affecting an estimated 5.5 million Australians, including 40% of all adults aged 50 years and above.

People who have 3 of the following and /or increased liver enzymes (shown through a blood test) will be likely to have **nonalcoholic steatohepatitis** (NASH) or a more severe form of fatty liver.



At present, NASH has **no approved treatment** over and above weight loss and often has no symptoms until it presents with liver failure, liver cancer or cardiovascular disease.

If you have NASH, ask your GP to refer you to a hepatologist at Nepean Hospital. Please contact Outpatients on 4734 2352 to make an appointment.

NASH Clinical trials at Nepean Hospital

All new medications must be tested in a series of clinical trials before they can be approved and prescribed by doctors. Without these clinical trials, no new drug treatments would be developed and few medical advances would be made.

If you have NASH and are eligible for these trials, then this is an opportunity for you to try a new drug that may work for you and to help others in future to use a drug that works for them. For more information please contact Gayathri on 4734 2319 or email NBMLHD-Gastro@health.nsw.gov.au .

Current clinical trials

1. *Randomised Control study of MGL-3196 (Resmetirom) in the treatment of Non-alcoholic steatohepatitis (NASH)*

Description
The study drug is **Resmetirom**, which is known to be a thyroid hormone receptor agonist. It has been noted to reduce hepatic fat.

The participant will have a 66% chance of receiving the study drug, with the remainder given placebo. It is a 4.5 year study with clinic visits every 3 months after the first 6 months.

Eligible participants:
Adults with NASH diagnosis F1, F2, F3 (which is confirmed by a hepatologist)

Population required

a) Metabolic features- Type 2 diabetes, large waist (or BMI >=30), High triglycerides, low HDL, hypertension (3 of these required)
b) Active hyperthyroidism excluded
c) No Contraindications for Abdomen MRI

2. *Randomised Control study of* lanifibranor *in the treatment of Non-alcoholic steatohepatitis (NASH)*

Description
The study drug is **lanifibranor**. It is a PPAR agonist. Previous clinical studies have shown lanifibranor induces anti-fibrotic, anti-inflammatory and beneficial vascular and metabolic changes in the body.

The participant has a 66% chance of getting the study drug, with the remainder getting placebo. Study duration –part 1 for 72 weeks and then continues for 7 years (part 2).

Eligible participants
Adults with NASH diagnosis F2 and F3 (which is confirmed by a hepatologist)
Population required

Stable doses diabetes medications and statins prior to liver biopsy and screening visit.

Insulin prohibited 3 months prior to screening and in part 1 of the study.

3. *Randomised Control study of* semaglutide *in the treatment of Non-alcoholic steatohepatitis (NASH)*

Description
The study drug is **semaglutide** which is a GLP-1 agonist. Semaglutide is currently used an anti-diabetic drug. This is a 5 year study.
The participant has a 66% chance of getting study drug, with the remainder getting placebo. Study duration is 5 years.

Eligible participants
Adults with NASH F3 (as diagnosed by a hepatologist)

4. *Randomised Control study of* NNC0194-0499 co-administered with semaglutide *in the treatment of Non-alcoholic steatohepatitis (NASH)*

Description
The study drugs are **NNC0194-0499 co-administered with semaglutide** and **NNC0174-0833**. These are FGF21 analogue, GLP-1 agonist and human amylin analogue respectively. 6 out of every 7 subjects will receive at least one active drug
The study duration is for 1 year.

Eligible participants
Adults who have been diagnosed with NASH F2, F3 and F4 (which is confirmed by a hepatologist)
Have a BMI > 25
Have a Fibro Scan® (transient electrography) score of >=9.1kPa

Keep your liver healthy

Created by Gayathri K – Research Coordinator