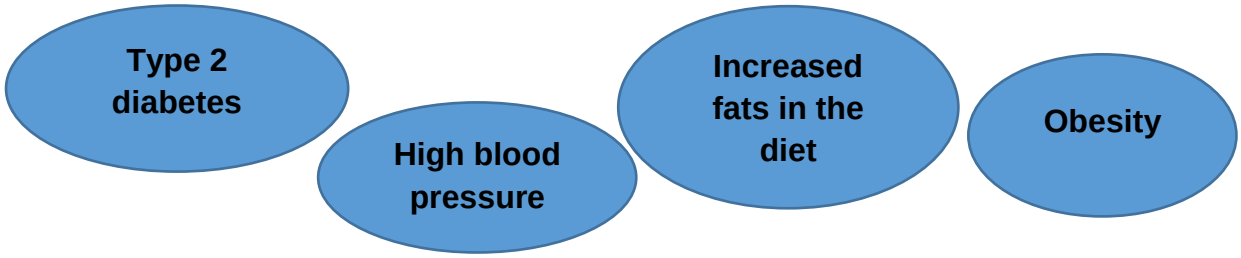
Did you know that people with increased fat in their liver due to Non-alcoholic fatty liver disease (NAFLD) can suffer from cardiovascular related death before suffering from liver related death?

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. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Nonalcoholic Steatohepatitis (NASH) and fibrosis

Description
The study drug is Elafibranor, which is known to be an insulin sensitiser. It has been noted to improve liver inflammation.

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

Eligible participants:
Males of ages 18-69 with NASH diagnosis (which is confirmed by a hepatologist)
If the individual has diabetes, then an HbA1c (a measure of overall diabetes control), done within the last 3 months, must be < 9.0%.

2. A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis

Description
The study drug is Obeticholic Acid. It is a modified bile acid used in the United States of America for treatment of primary biliary cholangitis. Current research has shown improvement of fibrosis in NASH after 18 months of treatment.

The participant has a 66% chance of getting the study drug, with the remainder getting placebo. It is a 7 year study with clinic visits every 3 months.

Eligible participants
Adults with NASH diagnosis (which is confirmed by a hepatologist)

3. A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis

Description
The study drug is Obeticholic Acid. This is a 2 year study with monthly clinic visits.
The participant has a 66% chance of getting study drug, with the remainder getting placebo in the first year. After the first year, all participants will receive study drug.

Eligible participants
Adults with NASH and compensated cirrhosis (as diagnosed by a hepatologist)

4. An Open-label study to assess the efficacy and safety of LM011 in subjects diagnosed with non-alcoholic steatohepatitis (NASH)

Description
The study drug is LM011. It is PKM2 inhibitor and thus has the potential to reduce cellular oxidative stress. This drug is also known as digoxin and has been used to treat heart failure and cardiac conditions for decades. Digoxin has been shown to reduce steatosis and liver injury in animal models.

The study runs over 5 months with 4 weekly visits. All participants are given study drug.

Eligible participants
Those aged 18-75 who have been diagnosed with NASH *and*
Have a BMI between 28 and 40 kg/m^2 *and*
Have an ALT and/or AST ≥ 2x upper limit of normal *and*
Have a Fibro Scan® (transient electrography) score of ≤12 kPa *and*
Should not have cardiovascular disease

Keep your liver healthy

Created by Gayathri K – Research Coordinator