

Ponticelli Treatment

This leaflet is to provide you with information about the Ponticelli regimen. If there is anything else you feel you need to know after reading this leaflet, please speak to your kidney doctor.

What is the Ponticelli regimen?

The Ponticelli regimen is a combination of drug treatments which is used to treat a kidney disease called membranous nephropathy. The Ponticelli regimen is named after Professor Claudio Ponticelli, an Italian doctor, who first proved that it was effective in treating people with membranous nephropathy. It is a 6-month course of treatment to dampen the immune system.

In the Ponticelli regimen, you will be given treatments:

- Steroids given by a drip into your veins called methylprednisolone.
- Steroid tablets called prednisolone.
- Cyclophosphamide tablets.

More details about these treatments are given in the later sections of this leaflet.

Why has my doctor recommended this treatment?

The Ponticelli regimen is given to people with membranous nephropathy whose condition is unlikely to get better without medication to dampen their immune system. If high level of protein leak continues, patients with membranous nephropathy are at risk of kidney decline and potentially kidney failure (35-50% risk by 10 years). The decision to start this treatment will be made by your kidney doctor after discussion with you.

What does the Ponticelli regimen involve?

Your treatment will be given to you over a 6-month period. In the first month you will be given steroids, and in the second month you will be given tablets called cyclophosphamide. This 2-month cycle is then repeated three times in total over 6 months.

Steroids: For the first 3 days at the start of every month of steroid treatment (month 1, 3 and 5) you will need a steroid drip/infusion through a cannula (small plastic tube) into a vein in your hand, which takes about an hour. This will be given to you in our **Renal Intervention and Treatment Area (RITA)** located on the 6th floor (Orange zone) at the Lister Hospital. If you would like to, you can have a friend or relative stay with you to keep you company while you are being treated. On the third day, you will be given steroid tablets to take for the rest of the month starting from day 4 onwards, i.e. from day 4 take steroid tablets each morning with food (this helps to avoid irritating the lining of your stomach).

Cyclophosphamide: This is an immunosuppression given as tablets for the full month. Weekly blood tests are needed to check your blood count has not been affected. Blood tests can be taken in hospital. **It is very important to attend your blood test appointments.**

It is important that effective contraception is used by both men and women during treatment with cyclophosphamide, and for 3 months after your treatment has ended. Cyclophosphamide should not be taken during pregnancy or whilst breastfeeding.

Cyclophosphamide may affect your fertility. Your doctor or nurse will discuss this with you before you start treatment.

You will also be given the following medications to take for the whole 6 months of treatment. These medicines help to reduce some of the side effects of the treatment:

- Co-trimoxazole tablets, which help to protect against certain lung infections.
- Famotidine or omeprazole to reduce the amount of acid in your stomach.
- Calcium and vitamin D to help protect your bones.
- Nystatin mouth solutions to help prevent mouth infections.

What are the benefits of the treatment?

In research studies, people with membranous nephropathy who are treated with the Ponticelli regimen have less protein in their urine (an important marker of kidney damage) and are less likely to develop kidney failure.

What are the side effects?

Steroids

These can cause side effects, but most people find they can cope with steroids for the short period of time they are taking the treatment. These side effects are normally short lived. The following is a list of more common side effects you may experience:

- A change in your sleep pattern, normally difficulty falling asleep. Taking the tablets in the morning should help with this.
- A change in your mood (feeling more up or down).
- Upset stomach including feeling sick.
- Heart burn or indigestion (we give you a medication called famotidine or omeprazole to help prevent this).
- Increased risk of stomach ulcers (we give you a medication called famotidine or omeprazole to help prevent this).
- A metallic taste in your mouth.
- An increased appetite.
- Weight gain - this is usually short term.
- A round appearance of your face.
- Fluid retention, ankle swelling and increased blood pressure. Your doctor will check your blood pressure.
- Increased risk of infection.
- Diabetes - your kidney doctor will measure your blood sugar level with each blood test when you come to clinic.
- Thinning of the bones (osteoporosis).
- Thinning of the skin.
- Changes in your eyesight due to conditions like glaucoma and cataracts.

- If you are diabetic, you might find your blood sugar levels will be higher, so we will advise you to measure your blood sugars more frequently. Your treatment for diabetes may need to be adjusted.
- Very rarely, some people can experience severe damage to their hip (known as avascular necrosis of the hip).

Cyclophosphamide

Common short-term side effects of cyclophosphamide include:

- Low white blood cell count (this can increase your risk of infection). Therefore, blood test monitoring is **very** important.
- Feeling sick or being sick – let us know if this is a problem as anti-sickness tablets can help.
- Irritation of the lining of the bladder and blood in the urine. **Tell your doctor straight away if this happens.** To reduce the risk of this happening, you should drink 8-10 glasses (2-3 litres) of water and/or non-alcoholic drinks a day.

Occasional side effects of cyclophosphamide include:

- Hair loss (usually grows back after stopping the drug).
- Diarrhoea.
- Mouth ulcers - mouthwashes can help, for example, chlorhexidine.
- A sore red mouth can occur. This can be prevented with miconazole or nystatin taken four times a day.
- Skin changes - skin may darken, but this is rare.
- Low platelet count (this can cause unexplained bruising or bleeding).

Cyclophosphamide can also cause:

- Infertility - this is unlikely to occur with only 3 months of treatment, but you should discuss this further with your kidney doctor.
- Damage to an unborn child - men or women who are taking cyclophosphamide should not try for a baby.
- Cancer (including bladder cancer) - cyclophosphamide causes a small increase in the risk of some cancers. Your kidney doctor will give you more information about this.

If you develop a high temperature whilst on the Ponticelli regimen, please contact the RITA or come to A&E and tell the doctors and nurses that you are receiving prednisolone or cyclophosphamide under the renal team.

How will I be monitored during the course of treatment?

You will be seen every 2-4 weeks in the renal clinic during treatment. During the months you are receiving cyclophosphamide you will need more frequent blood tests to monitor your blood count. Please plan with your kidney doctor where these blood tests will be done so they know where to look for the results.

What happens after my treatment?

After you have finished the course of treatment, your kidney doctor will review with you the results of your response to the treatment. This is done by measuring the leftover amount of protein in your urine and whether your kidney function has improved or stabilised, compared with before.

- If you no longer have any significant protein leak (urine PCR less than 30) you are in complete remission.
- If the protein leak has halved and urine PCR is now less than 350, you have achieved a partial remission.

Both complete and partial remission mean the chance of kidney failure in 10 years is probably reduced to 80-90%.

If you have not responded initially, you can sometimes see a delayed improvement over the next 6 months. However, if the membranous nephropathy still persists thereafter or is getting worse, further treatment options will be considered in clinic with your doctors.

Questions

Please speak to your kidney doctor if you have any questions or concerns about the Ponticelli treatment, or about any of the information in this leaflet.

Further information

The following websites have useful information about the treatment of membranous nephropathy:

- **National Kidney Foundation** www.kidney.org.uk
- **The Renal Association** www.ukkidney.org/rare-renal/homepage

Useful contact details

East and North Hertfordshire NHS Trust:

- Website www.enherts-tr.nhs.uk
- Telephone 01438 314333

Renal Intervention and Treatment Area (RITA):

- Telephone 01438 284775

Renal Pharmacy Team:

- Telephone 01438 284677
- Email - renalpharmacists.enh-tr@nhs.net

Secretary Telephone Numbers:

Dr Thompson

- Telephone 01438 284309

Dr Mathavakkannan

- Telephone 01438 284362

Leaflet information

Reference: Adapted from Oxford University Hospital's new patient information:
Ponticelli regimen for the treatment of Membranous Nephropathy, October 2015

**You can request this information in a different format or another language;
please speak to your doctor or nurse.**

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Modified Ponticelli Regimen Medication Record

Name: _____

Hospital No: _____

Month 1:

Methylprednisolone 500mg injections on days

Prednisolone tabletsmg each morning for 27 days.

To start and end

Month 2:

Oral cyclophosphamide tabletsmg daily for 30 days.

To start and end **Frequent blood tests**

Month 3:

Methylprednisolone 500mg injections on days

Prednisolone tabletsmg each morning for 27 days.

To start and end

Month 4:

Oral cyclophosphamide tabletsmg daily for 30 days.

To start and end **Frequent blood tests**

Month 5:

Methylprednisolone 500mg injections on days

Prednisolone tabletsmg each morning for 27 days.

To start and end

Month 6:

Oral cyclophosphamide tabletsmg daily for 30 days.

To start and end **Frequent blood tests**

My flu jab date:

My pneumonia jab date:

Please use this space to write down any notes or any questions you may like to ask: