WAHT-KD-019

Treatment of Inflammatory Bowel Disease with Biologics (in patients over 15 years of age)

Ustekinumab (Stelara) dosing and schedule

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Mode of action

Ustekinumab is a monoclonal antibody that targets and blocks the action of two cytokines called IL-12 and IL-23 which are important in the development of Crohn's disease.

Induction dose

This is given as an Intravenous infusion in 250ml Sodium Chloride 0.9% over 1 hour, dose is dependent on weight, see table below

Body weight at time of dosing	Recommended dose	Number of Stelara® 130mg vials	Volume to be removed from 250mL 0.9% Sodium Chloride bag
≤55kg	260mg	2	52mLs
>55kg to ≤ 85kg	390mg	3	78mLs
85kg	520mg	4	104mLs

How to reconstitute Ustekinumab

The vial of ustekinumab **should not** be shaken.

Visually inspect the vial for any particulate matter or discolouration prior to administration. The solution is clear and colourless to yellow light. Any deviation from this and the vial should not be used.

Calculate the number of Stelara® vials needed according to the patient's weight.

Withdraw and discard the volume of 0.9% Sodium Chloridefrom a 250mL infusion bag equal to the volume of Stelara® to be added i.e. discard 26mL of 0.9% Sodium Chloride per vial of Stelara® to be used. **See table**

Withdraw 26mL only from each vial of Stelara and add to the 250ml bag of 0.9% Sodium Chlordie the final volume of the infusion bag should be 250ml. Gently mix.

It should be administered via an in-line, sterile, non-pyrogenic, low protein binding 0.2micrometre filter giving set (supplied by pharmacy).

How to administer Ustekinumab

Via IV infusion over 1 hour, perform full set of observations once infusion is finished. Patient to stay for 1 hour observation afterwards with another set of observations at that point.

Maintenance

The next dose is given at 90mg subcutaneous injection at week 8 (after the IV infusion).

1. Patients who have shown an inadequate response will receive another dose at week 16. If there is no response at week 20 treatment should be stopped. If they have response they should go onto a maintenance dose of 90mg every 12 weeks.

2. Patients who have shown an adequate response at week 14 will receive another dose at week 20 and then 12 weekly thereafter.

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Loss of response

Ensure symptoms are due to active disease by performing faecal calprotectin or other investigations such as endoscopy, MRI, CT or VCE.

Those who lose response on 12 weekly injections can reduce to 8 weekly injections, if there is no improvement in symptoms 16 weeks after this the treatment should be stopped.

Blood monitoring

FBC, ESR, U&Es, LFTs and CRP at week 4 after I.V infusion and then every 12 weeks thereafter.

Pregnancy and Breast feeding

There is no adequate data on the use of ustekinumab in pregnancy therefore all women should be advised to use contraception throughout treatment and for at least 15 weeks after treatment finishes.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity

Ustekinumab is to be used during pregnancy only if the benefits clearly outweigh any potential risk to both the mother and foetus. Patients should be advised that the potential effects are unknown.

It is unknown whether ustekinumab is excreted in human breast milk. Animal studies have shown excretion of ustekinumab at low levels in breast milk. It is not known if ustekinumab is absorbed systemically after ingestion. Because of the potential for adverse reactions in nursing infants from ustekinumab, a decision on whether to discontinue breast-feeding during treatment and up to 15 weeks after treatment or to discontinue therapy with STELARA must be made taking into account the benefit of breast-feeding to the child and the benefit of STELARA therapy to the woman

Storage

Store in a refrigerator (2°C-8°C). Do not freeze.

Keep the vial or pre-filled syringe in the outer carton in order to protect from light.