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Barnsley Hospital NHS Foundation Trust | South West Yorkshire Partnership NHS Foundation Trust | South Yorkshire Integrated Care Board

Tinzaparin (Innohep®) for the Treatment and Prophylaxis of Venous Thromboembolism IN PREGNANCY

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (https://www.medicinescomplete.com/#/) and the SPC (https://www.medicines.org.uk/emc/) remain authoritative.

<table>
<tr><td>Background Information</td><td>Low Molecular Weight Heparins (LMWH's) such as tinzaparin are now widely used for a number of licensed and unlicensed indications including the prevention and treatment of venous (and sometimes arterial) thromboses in selected patient groups. The availability of LMWH's which are administered by subcutaneous injection only once or twice daily means that patients can often self-administer their anticoagulant.

This guideline is only for use in PREGNANT WOMEN whose CrCL is 20mL/min or above. Patients with severe renal impairment require additional monitoring and will be managed by the acute trust until further guidance can be written and approved.

Barnsley Hospital NHS Foundation Trust (BHNFT) now use tinzaparin (Innohep®) for the treatment and prophylaxis of all VTE associated indications.</td></tr>
<tr><td>BNF therapeutic class</td><td>2.8.1 Parenteral Anticoagulants</td></tr>
<tr><td>Indication</td><td>• Treatment of venous thromboembolism in pregnancy
• Prevention of venous thromboembolism or treatment of antiphospholipid syndrome in pregnancy

Not licensed for, but routinely used, in pregnancy</td></tr>
<tr><td>Dosage and administration</td><td>
<table>
<tr><th>Indication</th><th>Dose</th><th>Duration of Treatment</th></tr>
<tr><td>Treatment of venous thromboembolism in pregnancy (based on booking weight up to 36 weeks*)</td><td>• Under 40kg: 175units/kg ONCE a day
• 40-49kg: 8,000 units ONCE a day
• 50-59kg: 10,000 units ONCE a day
• 60-69kg: 12,000 units ONCE a day
• 70-84kg: 14,000 units ONCE a day
• 85-94kg: 16,000 units ONCE a day
• 95-109kg: 18,000 units ONCE a day
• 110-119kg: 20,000 units ONCE a day
• 120-129kg: 22,000 units ONCE a day
• 130-139kg: 24,000 units ONCE a day
• 140-154kg: 26,000 units ONCE a day
• Over 154kg: 175units/kg ONCE a day</td><td>Throughout pregnancy and for at least 6 weeks post-partum, should be continued until a total of at least 6 months treatment has been given.

Advice on adjustment to dosage in preparation for labour will be provided by haematologists</td></tr>
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<tr><td></td><td>
<table>
<tr><td>Prevention of venous thromboembolism or treatment of antiphospholipid syndrome in pregnancy (based on booking weight up to 36 weeks*)</td><td>• Under 50kg: 3,500 units ONCE a day
• 50-90kg: 4,500 units ONCE a day
• 91-130kg: 3,500units TWICE a day
• 131-170kg: 4,500 units TWICE a day
• Over 170kg: 7,000 units TWICE a day
• High prophylactic (intermediate) dose: 50 – 90kg: 4500 units 0.45mL TWICE a day</td><td>Throughout pregnancy and for 6 weeks post-partum. Consideration can be given to stopping at term in antiphospholipid syndrome associated with recurrent miscarriages.</td></tr>
</table>
*use booking weight up to 36 weeks, thereafter use 36 week weight

It is the responsibility of the obstetrics and midwifery teams to weigh the patient at 36 weeks and communicate any dose changes to primary care clinicians in a timely manner.

All patients will be supplied with 28 days of tinzaparin treatment upon initiation or discharge from BHNFT.

For women requiring the standard 6 weeks of tinzaparin prophylaxis in the post-natal period, the full supply will be made by Barnsley Hospital.

Referral will be made to GP's using the form in Appendix A.

Preparations available:
Innohep® is available as single-dose syringes in the following strengths/doses:

• 10,000units/mL as 2,500units/0.25mL; 3,500units/0.35mL; 4,500units/0.45mL
• 20,000units/mL as 8,000units/0.4mL; 10,000units/0.5mL; 12,000units/0.6mL; 14,000units/0.7mL; 16,000units/0.8mL; 18,000units/0.9mL

Where appropriate, primary care clinicians should prescribe tinzaparin in full pack sizes (multiples of 10 pre-filled syringes). This is to ensure the supply is received in an original manufacturer's pack (the packs are colour coded according to strength/dose of the pre-filled syringes) with the original patient information leaflet for patient safety.</td></tr>
<tr><td>Cautions and Contraindications</td><td>• History of Heparin Induced Thrombocytopenia
• Significant hepatic impairment
• Active gastric or duodenal ulceration or oesophageal varices
• Haemophilia and other inherited bleeding disorders / major bleeding disorders
• Thrombocytopenia with platelets <50 x 10^9/L
• Recent cerebral haemorrhage
• Severe hypertension
• Recent neurosurgery or eye surgery
• Acute bacterial endocarditis
• Hypersensitivity to tinzaparin</td></tr>
<tr><td>Pregnancy and breast feeding</td><td><u>Pregnancy</u>
Not known to be harmful, low molecular weight heparins do not cross the placenta.

<u>Breastfeeding</u>
The passage of tinzaparin into human breast milk is expected to be very low. The oral absorption of any trace amount of tinzaparin sodium in the breast milk to the infant is very unlikely. Tinzaparin can be used during breastfeeding.</td></tr>
<tr><td>Adverse Drug Reactions</td><td>• Primary care clinicians are not expected to monitor FBC as it is not routinely monitored for tinzaparin treatment in pregnancy unless the patient has had previous exposure to unfractionated heparin. However, if the patient presents</td></tr>
</table>

	within primary care with signs and symptoms of thrombocytopenia, skin reaction or new thrombosis within 14 days of starting therapy, HIT should be considered. Refer as an emergency to Medical SDEC for assessment and treatment. • Hyperkalaemia: Heparin inhibits aldosterone secretion and may cause hyperkalaemia (patients with diabetes, chronic renal failure, acidosis, raised potassium or taking potassium-sparing drugs most susceptible). Risk increases with duration of therapy. • Haemorrhage • Thrombocytopenia (monitoring for HIT required by secondary care as above) • Injection site reactions (consider change to alternative LMWH) • Osteoporosis (following long term use) • Skin necrosis and hypersensitivity reactions • Anaemia • Angioedema • Priapism • Stevens-Johnson syndrome • Thrombocytosis
Monitoring	Monitoring for heparin-induced thrombocytopenia (HIT) is not required in pregnant patients receiving LMWH unless they have had previous exposure to unfractionated heparin. Where appropriate to monitor for HIT, this will be carried out by BHNFT. Occasional patients require ongoing monitoring for hyperkalaemia, this will be assessed and communicated to the primary care clinicians by the initiating specialist. When the appropriate monitoring for HIT and hyperkalaemia (if applicable) have been performed (or following initiation if monitoring is unnecessary) the responsibility for re-prescribing the drug will pass to the patient's practice. The practice will be informed of this transfer of prescribing responsibilities and the patient provided with a further 2 weeks' supply of drug by the hospital pharmacy (minimum 4 weeks supply from treatment initiation). Patients at high risk of developing hyperkalaemia and renal impairment include those with pre-existing renal impairment and patients taking medication which may alter renal blood flow.
Interactions	Systemic salicylates, non-steroidal anti-inflammatory drugs (NSAIDs), clopidogrel, dipyridamole (increased risk of bleeding), ACE inhibitors (increased risk of hyperkalaemia), dextran, ticlopidine, systemic glucocorticoids, thrombolytics, anticoagulants. This is not a comprehensive list. Please see current BNF for complete information.
Additional information	Not applicable.
Ordering information	Not applicable.

Contact names and details

Contact Details	Telephone number	Email
Consultant Haematologists: Dr D. Chan-Lam Dr R Rashid	01226 730000	 dchanlam@nhs.net rumana.rashid@nhs.net
Consultant Obstetricians: Dr N Khanem Dr M Fawzy Dr Meena Srinivas Mr Sankar Mr Sarkar	01226 730000	 noor.khanem@nhs.net mfawzy@nhs.net meena.srinivas@nhs.net asankar@nhs.net r.sarkar1@nhs.net

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Mr Sharma Dr Chen		asharma2@nhs.net beefong.chen1@nhs.net
Medicines Information:	01226 432857	gilliansmith2@nhs.net or medicine.information1@nhs.net
Lead Anticoagulant Pharmacists: Umar Patel	01226 431460	umarpatel1@nhs.net

Equality and diversity

Tinzaparin is a LMWH that is porcine-derived, so it may not be suitable for some patient populations.

References

1. Summary of Product Characteristics (SPC) for tinzaparin (Innohep®) accessed via https://www.medicines.org.uk/emc/product/3632/smpc
2. BNF accessed via https://www.medicinescomplete.com/#/content/bnf/_380849985?hspl=Tinzaparin%20sodium
3. Royal College of Obstetricians and Gynaecologist Green Top Guideline 37a: Thromboembolic disease in Pregnancy and the Puerperium, reducing the risk, accessed via https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-37a.pdf
4. Royal College of Obstetricians and Gynaecologist Green Top Guideline 37b: Thromboembolic disease in Pregnancy and the Puerperium, Acute Management, accessed via https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-37b.pdf

https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

Development Process

This guidance has been produced by Tsz Hin Wong (Senior Pharmacist–Interface), Consultant Haematologists, BHNFT, and Consultant Obstetricians following an AMBER-G classification status of tinzaparin by the Barnsley Area Prescribing Committee. This guideline has been subject to consultation and endorsement by Dr D. Chan-Lam (Consultant Haematologist, BHNFT), Dr N Khanem (Consultant Obstetrician, BHNFT) and Mr J Bannister (Associate Medical Director and Chair of the Venous Thromboembolism Committee, BHNFT) and was ratified by the Area Prescribing Committee on 13th March 2024.

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Appendix A:

Tinzaparin in pregnancy: Transfer of prescribing from Hospital to Primary Care

- BHNFT will provide initial 28 days of tinzaparin and a sharps bin.
- BHNFT will monitor FBC at baseline, day 5 – 7 and again at day 12 – 14 where required (treatment doses).
- GP to continue prescribing tinzaparin as appropriate and organise sharps bins for safe disposal of used needles.
- The patient's medical care remains with the Hospital Consultant who initiated tinzaparin until accepted by the GP.

Affix PAS label or complete details

Patient Name:

Hospital Number:

NHS Number:

Date of Birth:								
	d	d	m	m	y	y	y	y

GP:

Practice:

Referring Consultant	
Referring Consultant:	Consultant Contact number:
Contact email:	Date of next antenatal appointment:
Indication for dalteparin	
VTE prophylaxis during pregnancy ☐	VTE treatment during pregnancy ☐
Treatment Information	
Patient booking weight: kg	Date treatment commenced:
Tinzaparin dose: units ONCE daily / TWICE daily (delete as appropriate)	
Duration of treatment: ☐ 6 weeks ☐ 3 months ☐ 6 months ☐ long term ☐ other:	
Tinzaparin to be administered by: ☐ Patient ☐ Carer ☐ District Nurse (Confirm that if patient/carer administering they have been counselled and trained on injection technique ☐)	
Additional relevant information:	
Form completed by	
Signature:	Print name:
Designation:	Contact number/bleep:
Sent by:	Time: Date: