Royal Berkshire NHS
NHS Foundation Trust

Paper APC16-7.5

Prescribing Guideline

Tinzaparin for Prophylaxis of Venous Thromboembolism during Pregnancy and the Puerperium

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Sign	Date
Maternity Governance	Chair		2016
Drug and Therapeutics Committee	Chair		2016
Area Prescribing Committee	Chair	Dr M Smith	02/03/16

Change History

Version	Date	Author	Reason
1	January 2016	Joanne Williams, Lead Pharmacist	New guideline

Introduction

This prescribing guideline has been prepared to support healthcare professionals in the implementation of shared care management of patients who have been prescribed tinzaparin for prophylaxis of venous thromboembolism during pregnancy and the puerperium.

Tinzapain is a low molecular weight heparin (LMWH) and used first line in all patients under the care of Obstetricians at the Royal Berkshire NHS Foundation Trust. Tinzaparin is licensed for the treatment and prevention of venous thromboembolism (VTE) and pulmonary embolism in adults including use in all trimesters of pregnancy.

The categories of patients suitable for general practitioner prescribing of tinzaparin using this guideline are as follows:

- Pregnant women at increased risk of VTE (as assessed using the proforma in the mother's hand held maternity notes, with a risk score of 3 or more)
- Recently delivered mothers with a VTE risk score of 3 or more as assessed by the VTE in pregnancy risk assessment tool used at Royal Berkshire NHS Foundation Trust.

This document should be used alongside guidance published by the Royal College of Obstetricians and Gynaecologists. Venous thromboembolism during pregnancy and the puerperium, reducing the risk.

Principles of shared care

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of tinzaparin can be shared between the consultant and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the consultant. If the consultant asks the GP to prescribe this drug, the GP must reply to this request as soon as practicable confirming whether or not they are happy to do so.

Sharing of care assumes communication between the consultant, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

Shared Care is only appropriate if it provides the optimum solution for the patient.

Note, the doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use**.**

Consultant Responsibilities	
1	Conduct VTE scoring to assess the need for tinzaparin.
2	Baseline investigations are conducted and if satisfactory, the patient is commenced on treatment.
3	Initiate therapy with a 14 day supply of medication.
4	Discuss with patient relevant information on; use, dose, duration, side effects and need for monitoring of medication.
5	Patient taught how to self-inject and information leaflet supplied.
6	Confirm shared care by letter with the patient's GP and include the shared care guideline.
7	Provide advice and support to the GP if problems occur during treatment.
8	Ensure patient aware of plan for prophylaxis around time of delivery and document in her hand held notes

General Practitioner Responsibilities	
1	Accept referral from secondary care to take on continued prescribing after initial 14 days.
2	Reinforce educational points provided by the hospital
3	Monitor for hyperkalaemia in those patients at higher risk of raised plasma-potassium concentrations including those with: diabetes mellitus, chronic renal failure, or raised potassium concentrations.
4	Keep records for all patients where tinzaparin has been prescribed to include: indication, concurrent conditions, dose, start date, expected duration, monitoring details, adverse incidents, consultants involved in treatment, any advice or actions.
5	Discontinuation of treatment if patient is experiencing severe side-effects and the hospital is not contactable
6	Conduct audit and review as deemed appropriate

Patient's role (or that of carer)	
1	Report to the specialist or GP if she does not have a clear understanding of the treatment and to report any concerns
2	Attend appropriate consultant and GP appointments
3	To have any required monitoring/tests carried out at regular intervals, as appropriate
4	Report any adverse events to the doctor who last supplied their injection.

SUPPORTING INFORMATION

TINZAPARIN SODIUM prefilled syringes

Dosage and administration
Dose is based on the patients booking weight:

Booking Weight	Dose	Supply
Less than 50kg	3500 units injected subcutaneously once daily	3500 unit prefilled syringe
50-90kg	4500 units injected subcutaneously once daily	4500 unit prefilled syringe
91-130kg	7000 units injected subcutaneously once daily	8000 unit prefilled syringe
131-170kg	9000 units injected subcutaneously once daily	10,000 unit prefilled syringe
Greater than 171 kg	75 **units/kg** injected subcutaneously once daily	Supply prefilled syringes only

Contraindications
- History of Heparin Induced Thrombocytopenia
- Renal impairment (calculated creatinine clearance <30mL/min)
- Significant hepatic impairment
- Active gastric or duodenal ulceration or oesophageal varices
- Haemophilia and other inherited bleeding disorders / major bleeding disorders
- Thrombocytopenia with platelets less than 50
- Recent cerebral haemorrhage
- Acute bacterial endocarditis
- Hypersensitivity to tinzaparin

Special Warnings
Only prefilled syringes should be used in pregnancy or breast feeding mothers. Multi-dose vials contain benzyl alcohol.

Pregnancy and breastfeeding
Tinzaprin may be used in all trimesters of pregnancy.

The use of tinzaparin is not licensed however, tinzapain is compatible with breast feeding. Studies have shown that heparin is not excreted into breast milk, and this is expected to be the case for all LMWH including tinzaparin. Heparins are not absorbed in relevant quantities from the gastrointestinal tract.

Drug interactions

- ACE inhibitors – increased risk of hyperkalaemia
- NSAIDs – possible increased risk of bleeding
- Angiotensin II receptor antagonists – increased risk of hyperkalaemia
- Anticoagulants – increased risk of bleeding
- Nitrates – anticoagulant effect of heparins reduced by infusion of glyceryl trinitate.

Side Effects

- Haemorrhage
- Thrombocytopenia
- Hyperkalaemia
- Injection site reactions
- Hypersensitivity reactions
- Skin necrosis

This list is not exhaustive – the manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary (BNF) should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Cost

Syringe	Cost per dose
3500 units	£2.77
4500 units	£3.56
8000 units	£4.76
10,000 units	£5.95

Further Information

If you have any concerns or if any problems occur contact the patients referring consultant. Contact details available on the referral form or clinic letters.

Royal Berkshire Foundation Trust Hospital, 0118 322511	
Lead Consultant	Samantha Low
Lead Midwife	Linda Rough. Extension: 7311
Medicines Information	Ext: 7803

References

Royal College of Obstetricians and Gynaecologists. Venous thromboembolism during pregnancy and the puerperium, reducing the risk. Green top guideline No 37a. 2015. Accessed via: www.rcog.org.uk

Leo Laboratories Limited. Summary of Product Characteristics (Innohep Syringe 10,000 IU). Last updated: 17-03-2015. Accessed on 11-1-2016. Via: www.medicines.org.uk

Schaefer C, Peters P, Miller RK. Drugs during Pregnancy and Lactation, 3rd edition. Elsevier; London: 2015.