Shared Care Agreement
*Tinzaparin for prophylaxis in pregnancy*

**Background**
Venous thromboembolism (VTE) remains a major direct cause of maternal death. A combination of risk factors or even a single risk factor may indicate the need for thromboprophylaxis during or after pregnancy.

All women should undergo an assessment of risk factors in early pregnancy (or before pregnancy if possible). For any pregnant women assessed as at risk of VTE, or with history of recurrent miscarriages or associated thrombophilias, antenatal thromboprophylaxis should begin as early in pregnancy as practical. Low molecular weight heparins (LMWH) are the agents of choice for antenatal thromboprophylaxis with tinzaparin being the formulary choice for LMWH in the Countess of Chester Hospital.

LMWH heparins for thromboprophylaxis should usually be administered throughout the antenatal period and for 6 weeks postnatally, however this shared care agreement applies to the antenatal period only. For women assessed as requiring thromboprophylactic LMWH in the postnatal period, the full supply will be made by the Countess of Chester Hospital.

**Indication**
Prevention of VTE during the antenatal period in pregnant women identified at high or intermediate risk.

Tinzaparin is not licensed for use in pregnancy, but systematic reviews and NICE have concluded that LMWH is a safe alternative to unfractionated heparin as an anticoagulant during pregnancy and, from a safety perspective, LMWH is preferred.

**Dose and preparations**
Syringe strength: Tinzaparin pre-filled syringe 10,000 UNITS/mL

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For patients with a weight over 91Kg, tinzaparin pre-filled syringes 20,000 UNITS/mL will be required to facilitate administration.

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<tr>
<th>Units</th>
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WEIGHT | TINZAPRIN DOSE
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<50 KG | 3,500 UNITS DAILY
50 – 90 KG | 4,500 UNITS DAILY
91 – 130 KG | 7,000 UNITS DAILY
131 – 170 KG | 9,000 UNITS DAILY
>170 KG | 75 UNITS / KG / DAY (syringe sizes used depends on the dose)

Please note:
- Doses used in pregnancy for prophylaxis differ from the usual licensed doses.
- The doses used are based on early pregnancy (booking) weight NOT the current bodyweight, unless there is a clinical concern about extreme increases in body weight.
- Doses are usually administered as a single daily dose at the same time each day.
- Tinzaparin should be administered throughout the antenatal period until the onset of labour.

**Administration**
Subcutaneous injection.

**Adverse effects**
- Haemorrhage.
- Injection site reactions - skin necrosis and hypersensitivity reactions.
- Thrombocytopenia – extremely rare when receiving thromboprophylaxis doses in pregnancy.
- 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.

**Contraindications and warnings**
- Platelets < 50 x 10⁹/L
- Previous heparin induced thrombocytopenia (HIT) or hypersensitivity to LMWHs
- Receiving therapeutic anticoagulation
- Clinical conditions such as HELLP or severe PET may be a contra-indication
- Acute stroke within 4 weeks (ischaemic or haemorrhagic)
- Uncontrolled hypertension
- Active peptic ulcer disease
- Severe renal disease (GFR < 30mls / min / 1.73m²): discuss with haematology and renal team
- Active antenatal / postnatal bleeding
- Severe liver disease with PT > normal range
Haemophilia or other known bleeding disorder (e.g., Von Willebrand’s Disease or acquired coagulopathy)

**Drug Interactions**
Non-steroidal anti-inflammatory drugs (NSAIDs), salicylates, clopidogrel, dipyridamole, thrombolytics, anticoagulants (increased risk of bleeding); ACE inhibitors (increased risk of hyperkalaemia). This list is not exhaustive; please see current BNF for complete information. N.B., Low dose aspirin (75mg daily) is NOT contraindicated.

**Monitoring requirements**
- A full blood count will be routinely taken as per standard practice during ante-natal care at booking and at 28 weeks: the results will be recorded in the patient’s hand held obstetric notes.
- No further routine monitoring of tinzaparin treatment is required for women prescribed tinzaparin for VTE prophylaxis in pregnancy unless there are clinical concerns about deterioration in renal function or extreme changes in weight.

**Cost**
As per latest Drug Tariff / BNF.

**RESPONSIBILITIES**

**Specialist responsibilities**
- To assess the patient for known risk factors for VTE. This assessment should be repeated if the woman is admitted to hospital for any reason or develops other inter-current problems.
- To commence tinzaparin for those patients identified as high risk requiring tinzaparin prophylaxis and to prescribe a minimum of the first 14 days of treatment.
- Educate and provide appropriate patient information on the risks of VTE in pregnancy and the role of tinzaparin in VTE prophylaxis.
- The midwifery team / or the anticoagulant nurse specialists will teach patients (or partner/relative/carer) how to self-inject, provide patient information leaflets on self-administration and will be responsible for checking injection sites at ante-natal reviews.
- Provide initial sharps bin and educate patient of disposal of syringes.
- To provide the GP with a summary of information (usually in a written letter) relating to the individual patient including the indication, dose and duration of treatment.
- To provide the GP with contact details in case of queries and clinical concerns.

**GP responsibilities**
- Ensure consultant has provided the appropriate information regarding the therapeutic issues relating to the patient’s clinical condition.
- To prescribe tinzaparin at the dose recommended by the specialist.
- If unwilling to continue prescribing tinzaparin, please complete the attached form (Appendix 1) stating reasons and return to the consultant as soon as possible.
- To ensure there are no interactions with any other medications initiated in primary care.
- To refer back to the specialist if there are any clinical concerns, development of adverse events or if compliance issues are evident.
- Discontinue the drug as directed by the specialist if required.
• To identify adverse events if the patient presents with any signs of these, and liaise with the hospital specialist where necessary. To report adverse events to the specialist and where appropriate the Commission on Human Medicines / MHRA (Yellow card scheme).

Patient responsibilities

• Discuss potential benefits and side effects of treatment with the specialist and GP, to identify whether they have a clear picture of these from the specialist and to raise any outstanding queries.
• Share any concerns they have in relation to treatment with tinzaparin.
• Report any adverse effects to their specialist or GP.
• Report to the specialist or GP if they do not have a clear understanding of their treatment.
• Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.

References


SPC available at: http://www.medicines.org.uk/emc/

British National Formulary www.bnf.org

Contacts

Consultant Haematologists Via secretaries 01244 265390

Obstetric team Week days 08.30 to 1700 01244 365130 (obstetric day unit)

Weekdays between 1700-8.30 and weekends 01244 365026 (labour ward)

This document should be read in conjunction with the Summary of Product Characteristics (SPC). The prescriber assumes legal responsibility for the drug.
Appendix 1: Shared Care Agreement – Tinzaparin for prophylaxis in pregnancy

To be completed by GP if not in agreement with continued prescribing

Name of patient ____________________________

Date of Birth ______________________________

Address ________________________________

Patient NHS No __________________________

I do not agree to prescribe tinzaparin for the above patient in accordance with the enclosed shared care protocol.

Reason for not wanting to continue prescription ____________________________________________________________

________________________________________________________________________________________________________

________________________________________________________________________________________________________

________________________________________________________________________________________________________

GP ____________________________ Date __________