Shared care Agreement

The use of tinzaparin for the prophylaxis of venous thromboembolic disease in obstetrics, for patients who are under the care of Central Manchester Foundation Trust.

Contents

1. Introduction:

Pregnant women are at increased risk of venous thrombo-embolic disease (VTE) (at least 1 per 1000 women). As such these women are risk assessed in the antenatal clinic at Central Manchester Foundation Trust (CMFT) and women who are deemed to be high risk for VTE are referred to the Joint Obstetric and Haematology Team (JOHT) at CMFT. This usually happens in the first trimester. High risk women may be prescribed tinzaparin for the duration of their pregnancy. Currently these women on tinzaparin would then be expected to return to the hospital for further supply of tinzaparin on a monthly basis. This leads to extra hospital appointments/visits for thromboprophylaxis that , for most women is a **standard** prophylactic dosage. For a small group of women (those with a BMI $\geq$ 35) initial monitoring and dose adjustment is required. However once the appropriate dose has been established this also remains the same through out the remainder of the pregnancy. The use of tinzaparin for prophylaxis of venous thromboembolic disease in obstetrics has been identified as an area suitable for **shared care prescribing**. Other Trusts have shared care guidelines for this indication.

Women who require tinzaparin for the **treatment** of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) will be under the care of the hospital. GPs **will not** be asked to continue care for this group of women under this shared care agreement.

2. Licensed indications:
Use in accordance with the CMFT local guidelines, JOHT haematology guidelines and the guideline for dosing of low molecular weight heparins in pregnancy. Please note this is an unlicensed indication, yet endorsed by the Royal College of Obstetricians and Gynaecologists (RCOG) as first line anticoagulant for use in pregnancy and the puerperium.

3. Therapeutic use and background:
Prophylaxis of VTE during pregnancy and the postnatal period in high risk patients. This is in accordance with guidance from NICE and the RCOG.

Standard dose: Tinzaparin 4500 units once daily

Prophylaxis may be continued for up to six weeks post partum. This will be based on an assessment of current and/or ongoing risk factors for VTE.

3.1 Patients with increased BMI, starting dose guide

Body Mass Index	35 -39	40-49	≥50
Dose of tinzaparin	6000– 8000 units	8000– 10000 units	12000 units

For more in-depth information please consult the CMFT guideline for dosing of low molecular weight heparins in pregnancy (Appendix 2).

Note that the above dosing regimen is for prophylaxis only. Women who are undergoing treatment for a DVT/PE will not be referred for shared care.

4. Cautions/contraindications:
- Current or history of heparin-induced thrombocytopenia (extremely rare).
- Generalised or local haemorrhagic tendency, known hypersensitivity to constituents, thrombocytopenia, including uncontrolled severe hypertension, severe liver insufficiency, active peptic ulcer, acute or sub acute septic endocarditis, renal failure, intracranial haemorrhage, or injuries and operations on the central nervous system, eyes and ears.

5. Adverse effects:
The most frequently reported undesirable effects are bruising (if extensive – arrange urgent FBC to assess platelets), injection site reactions, various skin reactions, reversible thrombocytopenia (extremely rare in pregnancy), headache and osteopenia (very rare when receiving prophylactic doses, with no additional risk factors for bone thinning).
Refer to the Summary of Product Characteristics (SPC) for full list of adverse effects.

6. Monitoring requirements:
No further monitoring will be required by the women referred to the GP for continuation of thromboprophylaxis, unless the patient is experiencing adverse effects.

7. Action to be taken if patient experiences adverse effects:
General advice can be sought from the JOHT or on-call obstetrician at CMFT. Contact via the hospital switchboard 01612761234.

GPs would be advised to do a full blood count and U+Es if any adverse effects are suspected.

Thrombocytopenia	Discontinue immediately and inform specialist promptly (within 24 hours) Please note this is extremely rare.
Hyperkalaemia	Inform specialist promptly and seek advice regarding continuation of therapy (again this is not something we have seen in obstetrics – not sure it should be sited.
Local skin reaction	If mild encourage site rotation and prescribe chlorphenamine. Continue injections and refer to JOHT for further advice. If more severe – stop injections, prescribe chlorphenamine and refer to JOHT for review.

8. Drug interactions:
The anticoagulant effect of tinzaparin may be enhanced by concomitant medication with other drugs affecting platelet function or the coagulation system, e.g. platelet aggregation inhibitors, thrombolytic agents, salicylates, non-steroidal anti-inflammatory drugs, vitamin K antagonists, dextrans, activated protein C. It is very unlikely that pregnant women would be using any of these drugs. Low dose aspirin (75mg daily) is NOT contraindicated.

9. Responsibilities:

9.1 Specialist responsibilities:

- Assessment of thrombotic risk and the need for thromboprophylaxis.
- Discussion with the women regarding the benefits and side effects of use of tinzaparin during pregnancy
- Initiate prophylactic tinzaparin in accordance with agreed clinical guidelines
- Training on injection technique and sharps disposal as self administration is to be undertaken by the woman and/or her partner.
- To communicate in a timely fashion with primary care colleagues and provide ongoing treatment plan (usually in written letter – including indication for use and dose of tinzaparin required)
- Address poor compliance with patient.

- Arrange any support (if appropriate) from community midwifery teams with regards administration.

9. 2 GP responsibilities:

- Reply to request for shared care as soon as practical
- Further supply of single dose syringes for duration of thromboprophylaxis
- Report any abnormal results to the specialist promptly, and seek advice regarding continuation of treatment. Follow the instructions in section 7 "what to do if the patient experiences any adverse effects".
- Ensure review of communication from secondary care on hospital attendances and treatment plan prior to prescribing the continuing supply.
- Alert the JOHT if a patient does not attend for repeat supply of medication. Poor compliance and/or an unwillingness to continue with treatment will be addressed by the JOHT.

9.3. Patient responsibilities:

- Ensure they do not run out of tinzaparin pre-filled syringes
- Correct storage of the injection
- Safe disposal of syringes when self administering
- Report any adverse effects to their GP and/or specialist whilst undergoing thromboprophylaxis. .
- Ensure they have a clear understanding of the indication for thromboprophylaxis and the prescribed dose.

10. Availability/Other special considerations:

- Tinzaparin is not licensed for thromboprophylaxis during pregnancy but the RCOG recommend that low molecular weight heparins are the drugs of choice for this indication.
- It is a relatively large molecule and therefore does not cross the placenta, thus presenting no risk to the fetus.
- Similarly, being a large molecule it is not expected to be excreted into breast milk, and would be inactivated in the GI tract if ingested, posing a negligible risk to the nursing infant.
- Studies on the long term use (courses up to 10 months) of tinzaparin for thromboprophylaxis in pregnant women have been published and no excess risk of osteoporosis was seen.

11. Appendix 1

Time line for a 'standard' patient.

1. 1st trimester
Patient is assessed in ANC using the standard VTE risk assessment proforma and is thought to be HIGH risk for a VTE.

2. Patient is then referred to the JOHT for further assessment and a decision to treat with tinzaparin is made, based on current guidelines and patient preference.

3. Baseline FBC and U+Es are performed and patient is commenced on a dose of tinzaparin.

4. If the patient is commenced on the 'standard dose' of 4500 units once daily, they will have a follow up FBC after one week to screen for heparin induced thrombocytopenia. If no problems are detected from the FBC no further investigations will be carried out and the patient is then suitable for primary care management.

5. If the patient has a BMI $\geq$ 35 they will be commenced on a different dose as per BMI (see dosing schedule above). They will have an anti Xa level checked within 1 week. . If, based on this result they are considered to be 'stable' the patient will then be suitable for primary care management. NO further monitoring, dose adjustment will be required. If further dose adjustment is required the woman will remain under the care of the JOHT until such time that an appropriate dose has been established.

6. Once patients are suitable for primary care management the JOHT will ensure that the following are completed:

- Patient will receive a 4 week supply of tinzaparin to ensure there is adequate time both for communication with the primary care team and for the woman to arrange a follow up supply from their GP.
- A letter will be sent to the GP stating indication for use, tinzaparin dose required and name and contact details for the consultant responsible for the patient's care at CMFT.
- Community midwives will be informed of the patient and the plan for shared care arrangements.
- A follow up appointment scheduled for approximately 36 weeks gestation, will be arranged to agree a delivery care plan.

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