HUTTmaternity
Hutt Valley Maternity Care

HUTT VALLEY DHB

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Nifedipine Tocolysis Regime Policy

Hutt Maternity Policies provide guidance for the midwives and medical staff working in Hutt Maternity Services. Please discuss policies relevant to your care with your Lead Maternity Carer.

Policy

Nifedipine is the preferred method of tocolysis for women admitted in threatened pre-term labour at Hutt Valley District Health Board.

The use of tocolytic therapy is at the discretion of the obstetric consultant on call. It is not usually utilised from 35 weeks gestation. The aim of the therapy is to **delay labour for enough time to administer a course of corticosteroids and / or to transfer the woman to a tertiary unit (Wellington women's Hospital).**
Nifedipine is a calcium channel blocker that decreases the tone in the smooth muscle of the myometrium and vasculature by inhibiting calcium influx across cell membranes. When used for tocolysis, calcium antagonists have fewer maternal side effects than other Tocolytics and have no adverse effect on fetal outcome.

Scope

All Midwifery and Obstetric medical staff
All Hutt Valley District Health Board access holders

Indications

Threatened pre-term labour prior to 35 (+ 0) weeks gestation where the consultant obstetrician on call decides that tocolysis is warranted.

Contraindications

Maternal
Hypotension/shock: Withhold if diastolic < 65 mmHg, or systolic <95 mmHg
Known allergic response to nifedipine
Concurrent use of a beta blocker (Risk of hypotension)
Concurrent use of hydralazine or magnesium sulphate (Risk of hypotension)
Concurrent use of a beta-mimetic infusion (risk cardiac failure)
When delivery is imminent
Known liver disease
Significant placental bleeding
Cardiac disease
Chorioamnionitis

Fetal
Gestational age > 35 weeks (+ 0 days)
Steroids completed within previous seven days

The fetus has congenital abnormalities that are incompatible with life
Where the fetus has died inutero
Where there is an indication to deliver the fetus
Suspected intrauterine infection
Suspected significant placental abruption
Severe growth restriction
Abnormal cardiotocograph

Use of Nifedipine

Side Effects

The most common side effects of nifedipine include:

- Palpitations
- Headaches and
- Facial flushing
- Hypotension may occur if the woman is dehydrated or if nifedipine is used in conjunction with hydralazine, magnesium sulphate or labetalol. Intravenous access is recommended prior to initiating treatment.
- Symptomatic hypocalcaemia can be precipitated when nifedipine is used in conjunction with magnesium sulphate.
- Less common side effects include constipation, dizziness, nausea, tachycardia, fatigue, peripheral oedema and increased liver enzymes.
    - Liver enzyme changes are not a concern with limited use however caution should be taken in those women who have known liver disease.

Changes in clinical circumstances

Ongoing clinical surveillance is critical.

- The clinical situation may change to one in which delivery is indicated e.g. chorioamnionitis
- Labour can occasionally be silently progressive when tocolysis is utilised. There should be a low threshold for reassessment of cervical changes if uterine activity persists or symptoms indicate that delivery may be imminent.

WARNING

If circumstances change that indicate delivery without labour (i.e. C/S), the background tocolysis can result in massive PPH secondary to atony. Consideration of timing of delivery will have to take into account indication for delivery and risk of PPH.

Complementary tocolytic agents

In extreme pre-maturity, ongoing uterine contractions may be suppressed with the additional prescription of indomethacin suppositories (50mg rectally every twelve hours).

Medicines Act 1981 Requirements

Nifedipine 5 mg is an unlicensed medication in New Zealand. The use of nifedipine for tocolysis is also unlicensed.

Therefore every woman who receives nifedipine tocolysis must be able to make an informed decision regarding its use. Her informed consent must be obtained and

documented in the clinical notes by obstetric team. **Standing orders do not cover unlicensed medicines.**

A record of women who are supplied this medication must be maintained (Section 29 requirement). A record is maintained in the delivery suite drug room.

Procedure for the administration of Nifedipine

Obtain informed consent prior to commencing therapy

Maternal observations

Obtain baseline observations

Assessment of uterine activity, cervical dilatation and station/descent of the presenting part should be made

A speculum should be passed and endocervical and high vaginal microbiology swabs taken for infection screening

Establish intravenous access

Take blood for FBC and Group and Hold

Observations

During the first hour, P and BP should be taken every 15 minutes before the next dose of short acting nifedipine is administered.

After the first hour P, BP and T should be checked every hour for 2 hours

Observations can then be every 4 hours as long as the woman is stable i.e. uterine activity is diminished

Fetal observations

A reassuring CTG trace should be obtained prior to the commencement of nifedipine therapy

Electronic fetal monitoring (EFM) should be continuous for the first hour and until contractions cease.

If the woman is not contracting then a reassuring CTG should be obtained 3 times per day during the course of the treatment

EFM is to recommence immediately if there is a change in clinical condition i.e.

The woman starts contracting again or the frequency or intensity of contractions increase

There is an increase in maternal temperature or pulse rate

Nifedipine dosing schedule (Refer Appendix 1)

Initial therapy **(refer to algorithm)**

The initial dose is 10 mg **short acting** nifedipine (2 x 5 mg capsules)

The woman is instructed to bite the capsules before swallowing. This assists in the absorption

If, after 15 minutes uterine contractions still persist, a second dose of 10 mg (2 x 5mg) short acting nifedipine is administered. The woman is again instructed to bite the capsule prior to swallowing

If contractions do not cease then this regime can be repeated every 15 minutes the maximum dose that can be administered in the first hour is 40 mg, four doses of 10 mg short acting nifedipine

Maintenance therapy (refer to algorithm)

A maintenance dose of **nifedipine retard 20mg** tablets is prescribed following initial therapy. The first dose of maintenance therapy is given 45 minutes after commencement of initial therapy (i.e. 45 minutes after the first dose of nifedipine short acting capsules). NB. Note change in nifedipine formulation from short acting capsules to retard tablets).
The amount of nifedipine retard that is prescribed varies depending on the tocolytic effect of the nifedipine capsules administered during the first hour. The dose of nifedipine retard that is prescribed can vary from between 60mg/24hours (i.e. 20mg every eight hours) to 160mg/24 hours (in divided doses every eight hours) until steroid administration is completed.

Recommended maintenance dosing schedule

MINIMUM NIFEDIPINE RETARD DOSING SCHEDULE
If no uterine activity after the short acting capsules:
20 mg Nifedipine long-acting every eight hours **(20 – 20 – 20)**

USUAL NIFEDIPINE LONG-ACTING DOSING SCHEDULE
Most women will respond to a dosing regimen of 40mg followed by 20mg then followed by a further 40mg given at eight hour intervals **(40 – 20 – 40)**

MAXIMUM NIFEDIPINE LONG-ACTING DOSING SCHEDULE
60 mg followed by 40mg followed by 60mg at 8 hourly intervals **(60 – 40 – 60)**

Should contractions return or increase the woman should be clinically reassessed. The obstetrician may decide to increase the dose during the 48 hour administration period up to the maximum dose or may consider alternative tocolytic measures
It is preferable to give nifedipine long-acting every eight hours to achieve a steady plasma level
Nifedipine retard should usually be discontinued 24 – 36 hours after the last steroid dose has been given as there is insufficient evidence to support its use after steroid administration is complete (Carr, 1999)
The last dose should be administered early in the day in order to assist with ongoing observations

Documentation
All medications administered to the woman must be prescribed on the Hutt Valley District Health Board medication chart.
All response to treatment must be documented in the notes.
Medicines Act requirements following the administration of Nifedipine short acting 5mg capsules must be maintained.
An antenatal assessment sheet must be maintained
EFM must be documented in the woman's notes

References

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Informed Consent

The right of a consumer to make an informed choice and give informed consent, including the right to refuse medical treatment, is enshrined in law and in the Code of Health and Disability Consumers' Rights in New Zealand. This means that a woman can choose to decline treatment, referral to another practitioner, or transfer of clinical responsibility. If this occurs follow the process map on page 18 of the Referral Guidelines (Ministry of Health, 2012).

Appendix one – Nifedipine tocolysis algorithm