

This applies to adult patients only

Loading Dose Worksheet for Intravenous Bivalirudin

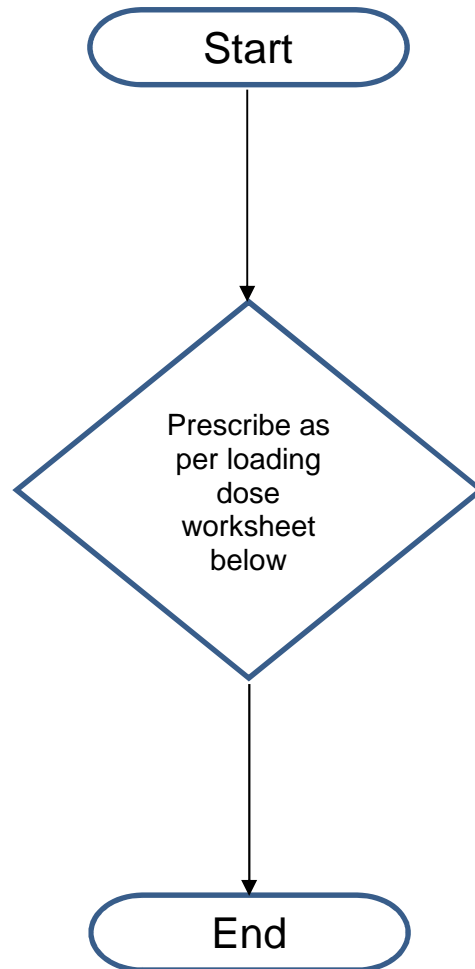
Key:

General Notes

GP/SWASFT

ED/MAU/SRU/Acute GP/Amb-Care

In-patient wards



1. Aim/Purpose of this Guideline

1.1. This loading dose worksheet is intended to guide medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of intravenous bivalirudin loading doses in adults

2. The Guidance

2.1. See the next page(s)

Loading dose worksheet for IV Bivalirudin

Administration

Dose

- Medical management of patients with ACS:
 - ◊ Initial bolus of 0.1mg/kg over 3-5 minutes, followed immediately by a continuous infusion at a rate of 0.25mg/kg/hr for up to 72 hours. If the patient proceeds to PCI, give an additional bolus of 0.5mg/kg before procedure and increase infusion to 1.75mg/kg/hr for the duration of procedure. Post-PCI, the infusion can be resumed at 0.25mg/kg/hr for 4 to 12 hours, if clinically necessary.
- For patients undergoing PCI (including patients with STEMI):
 - ◊ Initial bolus of 0.75mg/kg over 3-5 minutes, followed immediately by a continuous infusion of 1.75mg/kg/hr for the duration of procedure. The infusion can be continued at this rate for up to 4 hours post-PCI and then at a reduced dose of 0.25mg/kg/hr for an additional 4 to 12 hours, if clinically necessary.
 - ◊ **Please note** for patients undergoing PCI only: if eGFR is between 30-59mL/min/1.73m², then reduce rate of infusion to 1.4mg/kg/hr. The bolus dose remains the same.

Instructions for reconstitution and dilution

- Add 5 ml sterile water for injections to one vial of bivalirudin and swirl gently until completely dissolved and the solution is clear.
- Withdraw 5 ml from the vial, and add to a bag containing 45mLs of glucose 5% or sodium chloride 0.9% to give a final bivalirudin concentration of 5 mg/ml.

Other considerations

- Bivalirudin should be given concurrently with aspirin and clopidogrel.

Example Prescription (see overleaf for dose table)

- Based on 70kg adult for medical management of ACS.

EPMA Supplementary intravenous therapy prescription sheet										all patient use		
All infusions, infusion fluids, blood and plasma must also be prescribed in EPMA												
Date	Infusion solution	Name and dose of additive	Infusion volume	Duration of infusion	Infusion rate	Proposed start time	Prescriber signature	Infusion bag batch no.	Time actually started	Given by	Time finished	Pharmacy use
1/8/17	Glucose 5%	Bivalirudin	1.4mL	Stat	3 mins		Doctor (bleep)					
1/8/17	Glucose 5%	Bivalirudin		Continuous			Doctor (bleep)					

Monitoring

- Renal function (bivalirudin is contraindicated in eGFR less than 30mL/min/1.73m²).
- Monitor for bleeding as major adverse effect of bivalirudin.
- Monitor for signs of anaphylaxis.
- No other specific monitoring is essential, however, monitoring of normal cardiac parameters would be prudent.

Disclaimer: This worksheet is a guideline—there may be other safe ways of prescribing and administering this drug

Bivalirudin – Infusion Guidance Chart

Weight (kg)	Number of millilitres using 5 mg/mL concentration				
	Medical Management		For PCI		
	Bolus	Infusion	Bolus	Infusion	Infusion
	(100 mcg/kg)	(250 mcg/kg/hr)	(750 mcg/hr)	1.75 mg/kg/hr	1.4 mg/kg/hr
	(mLs)	(mLs/hr)	(mLs)	(mLs/hr)	(mLs/hr)
43-47	0.9	2.25	6.75	15.75	12.6
48-52	1	2.5	7.5	17.5	14
53-57	1.1	2.75	8.25	19.25	15.4
58-62	1.2	3	9	21	16.8
63-67	1.3	3.25	9.75	22.75	18.2
68-72	1.4	3.5	10.5	24.5	19.6
73-77	1.5	3.75	11.25	26.25	21
78-82	1.6	4	12	28	22.4
83-87	1.7	4.25	12.75	29.75	23.8
88-92	1.8	4.5	13.5	31.5	25.2
93-97	1.9	4.75	14.25	33.25	26.6
98-102	2	5	15	35	28
103-107	2.1	5.25	15.75	36.75	29.4
108-112	2.2	5.5	16.5	38.5	30.8
113-117	2.3	5.75	17.25	40.25	32.2
118-122	2.4	6	18	42	33.6
123-127	2.5	6.25	18.75	43.75	35
128-132	2.6	6.5	19.5	45.5	36.4
133-137	2.7	6.75	20.25	47.25	37.8
138-142	2.8	7	21	49	39.2
143-147	2.9	7.25	21.75	50.75	40.6
148-152	3	7.5	22.5	52.5	42

3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Medications Safety Pharmacist.
Tool	No specific tool. Datix will be used to identify clinical incidents.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Medicines Practice Committee. Clinical incidents on Datix will be reported to the senior nurse/manager in that area and will also be reported to the Medication Safety Group.
Acting on recommendations and Lead(s)	Actions from incident reports will be at a local level and may also result in broader actions, co-ordinated by the Medication Safety Group. Matrons/ward managers
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within the time frame specified in the action plan.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Diversity & Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Loading Dose Worksheet for Intravenous Bivalirudin.			
Date Issued/Approved:	November 2017			
Date Valid From:	November 2017			
Date Valid To:	November 2020			
Directorate / Department responsible (author/owner):	Bronwin Staple, Medicines Information Lisa Thomas, Medicines Information Ann Cardell, Medication Safety			
Contact details:	01872 252587			
Brief summary of contents	Guidance on the prescribing and administration of intravenous bivalirudin in adults.			
Suggested Keywords:	'Bivalirudin', 'Loading Dose', 'ACS'.			
Target Audience	RCHT ✓	PCH	CFT	KCCG
Executive Director responsible for Policy:	Chief Pharmacist.			
Date revised:	October 2017			
This document replaces (exact title of previous version):	Clinical Guideline for Bivalirudin in Adults – Loading Dose Worksheet.			
Approval route (names of committees)/consultation:	Medication Practice Committee.			
Divisional Manager confirming approval processes	<i>Head of relevant Division.</i>			
Name and Post Title of additional signatories	Not required.			
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}			
	Name:			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet		Intranet Only	✓

Document Library Folder/Sub Folder	Clinical / Pharmacy
Links to key external standards	None
Related Documents:	N/A
Training Need Identified?	N/A

Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
October 2011	V1.0	Initial Issue.	Ian Nicholls, Medication Safety Pharmacist
October 2012	V2.0	Clinical update.	Ian Nicholls, Medication Safety Pharmacist
August 2014	V3.0	Update to include EPMA changes and review practice.	Ian Nicholls, EPMA and governance Pharmacist
October 2017	V4.0	Clinical update.	Lisa Thomas, Medicines Information Pharmacist; Bronwin Staple, Medicines Information Lead Pharmacist.

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as <i>policy</i>) (Provide brief description): Loading Dose Worksheet for Intravenous Bivalirudin .	
Directorate and service area: All clinical areas	Is this a new or existing Policy? Existing.
Name of individual completing assessment: Lisa Thomas	Telephone: 01872 252587
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	This loading dose worksheet is intended to guide medical, nursing and pharmacy staff in the safe and appropriate prescribing and administration of intravenous bivalirudin loading doses in adults.
2. Policy Objectives*	To ensure RCHT complies with the requirements of the NPSA RRR018: <i>Preventing fatalities from medication loading doses.</i>
3. Policy – intended Outcomes*	Reduction in the risk associated with the prescribing and administration of intravenous bivalirudin loading doses in adults.
4. *How will you measure the outcome?	Review of Clinical Incident Reports.
5. Who is intended to benefit from the policy?	All adult inpatients within the Trust.
6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No. Medications Safety Group.

7. The Impact			
Please complete the following table.			
Are there concerns that the policy could have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	Policy for all patients
Sex (male, female, trans-gender / gender reassignment)		✓	Policy for all patients
Race / Ethnic communities /groups		✓	Policy for all patients

Disability - Learning disability, physical disability, sensory impairment and mental health problems		✓	Policy for all patients
Religion / other beliefs		✓	Policy for all patients
Marriage and civil partnership		✓	Policy for all patients
Pregnancy and maternity		✓	Policy for all patients
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	Policy for all patients
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> • You have ticked “Yes” in any column above and • No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or • Major service redesign or development 			
8. Please indicate if a full equality analysis is recommended.		Yes	No ✓
9. If you are not recommending a Full Impact assessment please explain why.			
It is not required as the guideline does not have a differential impact on any group.			
Signature of policy developer / lead manager / director		Date of completion and submission November 2017	
Names and signatures of members carrying out the Screening Assessment	1. Lisa Thomas 2. Bronwin Staple		

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead,
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed _____

Date _____