

Patient Agreement to Systemic Therapy: Consent Form	
VTD	
Patient's details / addressograph:	<input type="checkbox"/> Male <input type="checkbox"/> Female
	Special requirements (e.g. other language/other communication method)
	Consultant:

Name of proposed course of treatment: VTD **Bortezomib 2-weekly schedule:**

Bortezomib (Velcade®) s/c injection twice a week on days 1, 4, 8 and 11, Thalidomide oral once daily continuously, Dexamethasone oral once daily on days 1 and 2, 4 and 5, 8 and 9, 11 and 12
Repeated every 21 days for up to 4 cycles

 Bortezomib once weekly schedule:

Bortezomib (Velcade®) s/c injection once a week on days 1, 8, 15 and 22, Thalidomide oral once daily continuously, Dexamethasone oral once daily on days 1 and 2, 8 and 9, 15 and 16, 22 and 23
Repeated every 28 days for up to 4 cycles

Macmillan/CRUK leaflet given Thalidomide Information and counselled on pregnancy prevention

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, follow-up appointments) and location.

The intended benefits

- Disease control - the aim is not to cure but to control the disease. The aim is to improve both quality of life and survival
- Induction – therapy given in the acute state of the disease, aiming to reach response and to introduce a control of the disease

Significant, unavoidable or frequently occurring risks:

Common side-effects: bruising or bleeding, anaemia (low number of red blood cells), numbness or tingling in hands or feet, low blood pressure, dizziness or feeling faint when standing, feeling sick (nausea), diarrhoea, constipation, rash, dry skin, tiredness, sleepiness and feeling weak, slower heart rate; local skin irritation and redness after bortezomib injection

Side effects related to dexamethasone: irritation of the stomach lining, increased appetite, changes in blood sugar levels, fluid retention, changes in behaviour (mood swings, difficulty sleeping, anxiety or irritability).

Less common but potentially life threatening side-effects: severe infection causing organ failure

Other less common side-effects include: sore mouth and ulcers, taste changes, irritation of the bladder lining, fluid retention and heart failure

Cancer can increase your risk of developing a blood clot (thrombosis), and having chemotherapy may increase this risk further. A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain - you must tell your doctor straight away if you have any of these symptoms.

Some chemotherapy drugs can damage women's ovaries and men's sperm, with risk of infertility and early menopause in women. I have warned the patient about the likelihood of:

- early menopause in women infertility (in men and in women)

Thalidomide can damage the development of a baby in the womb (foetus), leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women. The patient has been advised not to become pregnant / not to get a partner pregnant during the period of treatment, and for 12 months (women) / 6 months (men) after treatment has completed.

Any other risks:

Clinician Signature	
Signed.....	Date
Full Name (print) /	Job Title.....
(Forename)	(Surname)

Statement of patient

Patient Signature	
Please read this form carefully, which describes the benefits and risks of the proposed treatment. You have the right to change your mind at any time, including after you have signed this form.	
I agree to undergo chemotherapy. I understand the treatment and am aware of the potential side-effects arising from this treatment.	
I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.	
Signed.....	Name.....
Date.....	
A witness should sign below if the patient is unable to sign but has indicated his or her consent.	
Signature	Date
Name (PRINT)	

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed Name (PRINT) Date.....

Confirmation of consent (to be completed by the chemotherapy nurse when the patient attends for the first cycle)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the treatment to go ahead.

Signed Name (PRINT) Date.....

Copy accepted by patient: yes/no (please ring)
Copy to be retained in patient's notes

Reason for Update: N/A	Checked and approved by Consultant: Dr E Grey-Davies
Version: 1	Date: 4.7.17