THE SHEFFIELD AREA PRESCRIBING GROUP

Shared Care Protocol

For

Riluzole

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This is guidance on the management of a condition not a commissioning arrangement

Riluzole Shared Care Protocol

Statement of Purpose

This shared care protocol has been written to enable the continuation of care by primary care clinicians of adult patients initiated and stabilised on riluzole by neurologists at STH. Primary care will only be requested to take over prescribing of riluzole within its licensed indication unless specifically detailed otherwise below.

Responsibilities of consultant clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent. This is particularly important for unlicensed products.
- To initiate riluzole in appropriate patients
- To monitor as above
- To prescribe the first 3 months supply or until patient stable, assessing adherence and checking for any side effects
- To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol
- To advise the GP regarding continuation of treatment, including the length of treatment
- To discuss any concerns with the GP regarding the patient's therapy
- The patient to remain under the consultants care whilst ever the patient is being prescribed riluzole

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care agreement
- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To undertake monitoring as per shared care protocol above
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual medication review
- In the event that the GP is not able to prescribe, or where the share care is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly by a secure method on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems: http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording_SIDs_on_practice_clinical_systems%20.pdf

Responsibilities of patients/carers

- Present rapidly to the GP or specialist should their clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or GP whilst taking riluzole.
- To read the drug information given to them
- To take riluzole as prescribed
- Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Indication

Motor neurone disease (MND) is the term used to describe progressive muscular atrophy (PMA) and amyotrophic lateral sclerosis (ALS) which includes Progressive Bulbar Palsy.
ALS, which is characterised by both upper and lower motor neurone signs, is the most common form of MND, accounting for 65% to 85% of all cases. Adult-onset MND is characterised by progressive degeneration of the motor neurones of the brain, brain stem or spinal cord, starting insidiously with symptoms and signs including stumbling, foot drop, weakened grip, slurred speech, cramp, muscle wasting, twitching and tiredness. Other symptoms of MND include muscle stiffness, paralysis, incoordination and impaired speech, swallowing and breathing. Most individuals die from ventilatory failure, resulting from progressive weakness and wasting of limb, respiratory and bulbar muscles within approximately 3 years of the onset of symptoms.

Riluzole is licensed to extend life or the time to mechanical ventilation for individuals with the ALS form of MND.

Selection of patients

Patients will be: diagnosed; assessed for suitability of treatment with riluzole; have benefits and side effects discussed; will have treatment initiated and have baseline and initial monitoring done by neurologists.
Patients will only be transferred to the primary care clinician on confirmation that liver function tests (LFTs) are within the normal range at month 3.

Dosage

50mg every 12 hours

Administration - swallowing difficulties:
All patients who develop swallowing difficulties will be referred to Speech and Language therapists for an assessment. The tablets can be used in an off label manner, i.e. crushed and mixed with soft food e.g. yoghurt or puree to aid swallowing. Tablets crushed onto food should be eaten within 15 minutes as there is no stability data available for this method of administration. Use crushed tablets with care as they may have a local anaesthetic effect in the mouth.
STH has up to 5 years' experience of crushing non-proprietary tablets without adverse events.

A licensed oral suspension is available if crushing tablets is unacceptable or technically too difficult. However, the oral suspension is currently significantly more expensive than the tablets.

Administration – enteral tubes:
The tablets can be crushed and dispersed in water for enteral tube administration. Give immediately. Riluzole may block enteral feeding tubes, so ensure that the tube is flushed well after each dose.
The oral liquid is licensed for administration via enteral feeding tubes. Further dilution is not necessary.

Duration of treatment
Indefinite

Contraindications
Hepatic disease **or baseline** transaminases greater than 3 x the ULN.
Pregnancy, breast feeding.

Full list of side-effects / contraindications is given in the riluzole summary of product characteristics (SPC), available from www.emc.medicines.org.uk .

Side–effects

The details below are not a complete list and the BNF and the SPC remain authoritative

Nausea, vomiting, weakness, tachycardia, somnolence, headache, dizziness, vertigo, pain, paraesthesia, neutropenia and alterations in liver function tests. Transient increases in ALT can occur in the first 3 months of treatment, with levels returning to below twice the upper limit of normal after 2 to 6 months while treatment continues.

Monitoring

Monitoring requirements

Secondary Care
LFTs before and during therapy every month for the first 3 months. If within normal range patients will be transferred to primary care.

Primary Care
LFTs every 3 months for a further 9 months, and annually thereafter. GPs may be asked to take bloods in the first 3 months.

ALT levels should be measured more frequently in patients who develop elevated ALT levels.
Riluzole should be discontinued if ALT levels **increase** to 5 x the upper limit of normal (ULN). There is limited experience with dose reduction or re-challenge in these patients.
Patients should be warned to report any febrile illness to their physicians. White blood cell counts should be checked and riluzole discontinued if :
WBC $<3.5 \times 10^9/l$
Neutrophils $<2 \times 10^9/l$

Patient should be warned to report new or worsening respiratory symptoms to their doctor, particularly dry cough and/or dyspnoea. Chest radiography should be performed, and in case of findings suggestive of interstitial lung disease, riluzole should be discontinued immediately and respiratory advice sought.

Interactions

The details below are not a complete list and the current BNF and the SPC remain authoritative.

No clinical data available but since riluzole is extensively metabolised by the enzyme cytochrome P450 1A2, inhibitors (e.g. theophylline, quinolones) and inducers (e.g. rifampicin, omeprazole) of this enzyme could potentially affect the rate of elimination. If a PPI is required, lansoprazole could be considered as this does not have the same effect on cytochrome P450 1A2 as omeprazole.

Re-Referral guidelines

Patients will remain under the care of neurology clinicians at STH and will be reviewed in outpatient clinics every 2-3 months but this will depend on health of individual patients.

Financial implications

Commissioning of riluzole has been agreed and is included in the LCS-Services Over and Above Essential and Additional General Practice (not covered by a current LCS or DES).

Support, education and information

Contact the consultant neurologist who is responsible for the patient as detailed in patient letters via RHH switchboard.

MND nurse, Theresa Walsh, is also available for advice on 0114 222 2266

Information for patients

http://www.mndassociation.org/Home

References

NEWT Guidelines for administration to patients with enteral feeding tubes or swallowing difficulties, Third edition, February 2015

Full list of side-effects is given in the riluzole summary of product characteristics (SPC), available from www.emc.medicines.org.uk .

Useful links / Additional information (e.g ordering information)

NICE

https://www.nice.org.uk/guidance/ta20

https://www.nice.org.uk/guidance/ng42

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(Template riluzole letter to GP)

Dear Doctor

RE: …….. DOB: …… NHS No. ……..

Address: ……..

Your patient has being started on and completed 3 months treatment with riluzole without any significant problems.
This treatment can be prescribed by GPs under the Traffic Light System under the “shared care” arrangements. This shared care protocol has been approved by the Sheffield Area Prescribing Group.
http://www.intranet.sheffieldccg.nhs.uk/medicines-prescribing/shared-care-protocols.htm
Riluzole is the treatment of choice in motor neurone disease; it is the only drug currently licensed for this condition and the only medication proven to be effective in clinical trials. Riluzole has been shown to slow the progression of motor neurone disease and improve life expectancy, on average between 2-3 months although in clinical practice benefits vary between individual patients. The use of riluzole for motor neurone disease is recommended by the National Institute for Health and Care Excellence (Technology appraisal 20).
As part of shared care arrangements please can you monitor and prescribe for your patient, as per the shared careprotocol, found here: (insert link)
Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by secure e mail to …….

Do not hesitate to contact us if you have any concerns.

Yours sincerely

Clinician’s Name

Clinician’s Title

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IMPORTANT REMINDER

The prescribing doctor is responsible
for monitoring the patient on the medication being prescribed

_____*please tear here, return to address or secure e mail*

_____

RE: …… DOB: …… NHS:……..

Address: ……..

☐ I AGREE to take on shared care of this patient

☐ I DO NOT AGREE to take on shared care of this patient

Signed ……
GP Practice……
Date……

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