

Reolysin®

Horizons Infosheet Clinical trials and novel drugs

This Horizons Infosheet provides information on Reolysin, an oncolytic virus being investigated for the treatment of myeloma.

The Horizons Infosheet series provides information relating to novel drugs and treatment strategies that are currently being investigated for the treatment of myeloma. The series also aims to highlight the considerable amount of research currently taking place in the field of myeloma.

The drugs and novel strategies described in the Horizons Infosheets may not be licensed and/or approved for use in myeloma. You may, however, be able to access them as part of a clinical trial.

What is Reolysin?

Reolysin, also known as pelareorep, is a type of oncolytic virus being investigated for the treatment of myeloma and various other cancers. Oncolytic viruses infect and kill cancer cells. At the same time, they cause the immune system to launch an immune response against the cancer cells, so their action against the cancer cells is increased.

How does Reolysin work?

When Reolysin infects a myeloma cell, it creates copies of itself in the cell until the cell bursts. This causes the myeloma cell to die and release the virus into the surrounding area (Figure 1). The virus then goes on to infect and kill other myeloma cells. In healthy cells, the Reolysin does not make copies of itself inside the cell, and the cell is not damaged.

In addition to directly killing myeloma cells, Reolysin also causes the immune system to launch an immune response against myeloma cells. The immune system is made up of specialised cells, tissues and organs which can identify and kill faulty or abnormal cells in the body, and protect the body from foreign organisms (such as bacteria or viruses).

How is Reolysin given?

Reolysin is given as a slow intravenous (IV) infusion. How often Reolysin is given (i.e. the number of 'doses') is still being investigated in clinical trials.

What evidence exists to support the use of Reolysin in myeloma?

Initial findings from a small trial of Reolysin given on its own to 12 multiply relapsed myeloma patients showed it to be well tolerated but with only very limited clinical response.

Small-scale clinical trials are now looking at the effects of Reolysin in combination with other anti-myeloma drugs. Initial indications are that Reolysin has some effect

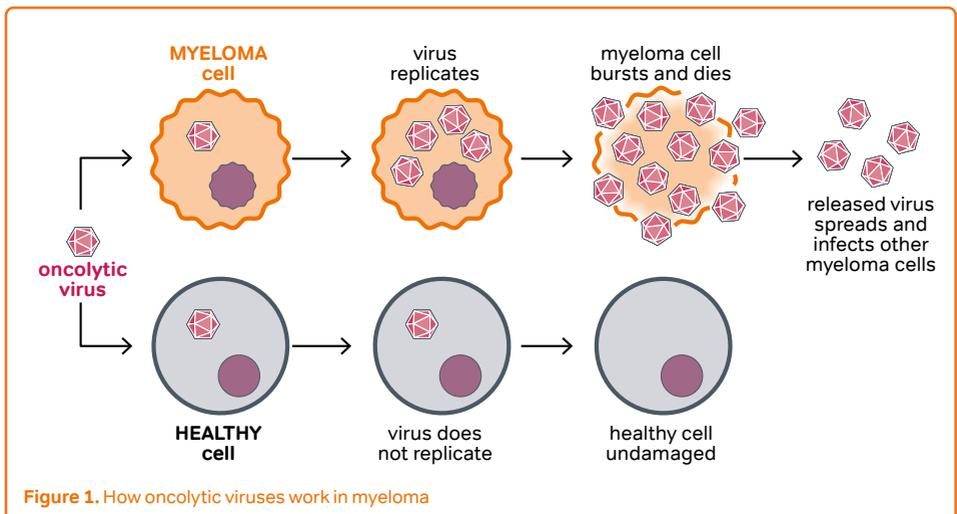


Figure 1. How oncolytic viruses work in myeloma

in myeloma when combined with dexamethasone and either bortezomib (Velcade®) or carfilzomib (Kyprolis®).

What are the possible known side effects of Reolysin?

Reolysin is a laboratory-purified version of a naturally occurring virus of the reovirus type. Naturally-occurring reoviruses cause only mild or no symptoms, and most people have been exposed to them at some point.

The most commonly seen side effects of Reolysin in initial clinical trials with myeloma patients have been similar to those seen with natural reovirus infection: mild to moderate diarrhoea, fatigue, headache and flu-like symptoms.

Other side effects seen to date have included reduced white blood cell and platelet counts. Patients given Reolysin in combination with carfilzomib and dexamethasone have also developed what is called a “cytokine storm”. This is when the immune system produces too much of chemical messengers called cytokines, which can cause severe effects on the body.

Because investigation of Reolysin in myeloma is still at an early stage, new side effects may emerge which have not yet been reported.

Is Reolysin currently available in any UK clinical trials?

For an up-to-date list of UK clinical trials involving Reolysin, visit the Myeloma Trial Finder on myeloma.org.uk

To be enrolled on a clinical trial, patients have to meet certain conditions known as eligibility criteria. You should speak to your doctor in the first instance if you are interested in taking part in a trial.

If you are considering taking part in a clinical trial your doctor will discuss in detail the risks and benefits for you. They will give you detailed information to enable you to make an informed decision about whether to take part.

Availability of Reolysin in the UK

Reolysin is not currently available for use in myeloma in the UK and is only accessible to patients as part of a clinical trial.

Before a drug or treatment can be widely used, it must first be licensed as safe and effective. This is usually done by the regulatory authorities

at a European level and involves a review of evidence from large-scale clinical trials.

Normally, the licensed drug or treatment must then be approved by a UK drug appraisal body before it can be routinely prescribed by NHS doctors. The drug appraisal process differs from licensing – it compares how effective the newly-licensed drug or treatment is to existing NHS treatment and decides whether it offers the NHS good value for money.

The main body responsible for carrying out drug appraisals in England and Wales is the National Institute for Health and Care Excellence (NICE). NICE recommendations are usually adopted in Northern Ireland. Scotland's drug appraisal body is the Scottish Medicines Consortium (SMC).

For more information see the **Health Technology Assessment (HTA) Infosheet** from Myeloma UK

Future directions

Early stage clinical trials of Reolysin in myeloma are ongoing. Reolysin is being studied in combinations

with lenalidomide (Revlimid®), pomalidomide (Imnovid®), bortezomib and carfilzomib.

These clinical trials are looking at how well the different combinations are tolerated and how much they activate the immune system.

Because Reolysin is a virus, the patient's immune system will attack the virus itself and clear it from the body. The aim of any combination treatment with Reolysin is to get the best possible effect on the myeloma cells, while at the same time limiting how fast the viruses are cleared away by the patient's immune system.

Summary

- Reolysin is a new treatment that is being investigated for the treatment of myeloma
- Reolysin is a type of naturally occurring virus which works by attacking cancer cells, and by triggering an immune response against the cancer cells
- Clinical trials are at an early stage, and include trials of combination treatments with Reolysin
- Side effects seen with Reolysin in myeloma have included mild effects such as diarrhoea, fatigue and flu-like symptoms

- There have also been reports of severe immune reactions when Reolysin was combined with other drugs. New side effects may emerge which have not yet been reported, and the side effects may depend on the specific drug combination
- Reolysin is not yet widely available, because it has not been licensed and approved for use in myeloma. However, patients may be treated with it as part of a clinical trial

About this Infosheet

The information in this Infosheet is not meant to replace the advice of your medical team. They are the people to ask if you have questions about your individual situation.

For a list of references used to develop our resources, visit myeloma.org.uk/references

We value your feedback about our patient information.

For a short online survey go to myeloma.org.uk/pifeedback or email comments to myelomauk@myeloma.org.uk

Other information available from Myeloma UK

Myeloma UK has a range of publications available covering all areas of myeloma, its treatment and management. Download or order them from myeloma.org.uk/publications

To talk to one of our myeloma Information Specialists about any aspect of myeloma, call our Myeloma Infoline on **0800 980 3332** or **1800 937 773** from Ireland.

The Infoline is open from Monday to Friday, 9am to 5pm and is free to phone from anywhere in the UK and Ireland.

Information and support about myeloma is also available around the clock at myeloma.org.uk

Notes

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We're here for everything a diagnosis of myeloma brings

Get in touch to find out more about how we can support you

Call the Myeloma Infoline on

 **0800 980 3332**

Email Ask the Nurse at

 **AskTheNurse@myeloma.org.uk**

Visit our website at

 **myeloma.org.uk**

Myeloma UK

22 Logie Mill, Beaverbank Business Park,
Edinburgh EH7 4HG

 0131 557 3332

 myelomauk@myeloma.org.uk

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