RECOVERY Central Coordinating Office
Nuffield Department of Population Health
Richard Doll Building, Old Road Campus
Roosevelt Drive, Oxford, OX3 7LF

Tel: 0808 164 4060
Email: recoverytrial@ndph.ox.ac.uk
Website: www.recoverytrial.net

****

****

00001
000001\322 *

ID Number: **********

Dear parent/guardian of ********** ,

Participation in the RECOVERY trial

On behalf of the University of Oxford and local hospital trial teams, we wish to thank you for agreeing that ********** could take part in the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial. This is the largest clinical trial in the world to find effective treatments against the effects of COVID-19 for patients in hospital.

We are writing to update you on the results of the part of the trial that aimed to find an effective treatment for children in hospital with a condition called paediatric inflammatory multisystem syndrome (PIMS) because of a COVID-19 infection. PIMS causes inflammation in the body when the immune system fights off the virus but then overreacts to affect other parts of the body.

You can read more about the the trial and the treatments tested on the second page of this letter and on the RECOVERY website at www.recoverytrial.net/news.

Results of the trial

Your child's participation in RECOVERY has helped us to find out that:

- Initial treatment with methylprednisolone is effective at reducing the length of time that children with PIMS need to spend in hospital;
- If symptoms do not improve, tocilizumab is an effective treatment for reducing the length of time that children with PIMS need to spend in hospital;
- Immunoglobulin was not an effective treatment for PIMS;
- Some children who were given methylprednisolone and tocilizumab needed more heart support medicines than children not given these added treatments, but all the treatments were found to be safe for children.

NHDA3_1_T260554_010824\000001\1\1of4\

IRAS 281712 REC Ref 20/EE/0101 The study was funded by UK Research and Innovation, the National Institute for Health and Care Research, and Wellcome. It is registered at ISRCTN50189673.

We were not able to find out if anakinra was effective because the number of children being admitted with PIMS became very small.

The trial 'in a nutshell'

The only way to find out whether or not a potential treatment works is to assess it in a randomised controlled trial. This means that a number of similar people are randomly selected to either receive a treatment or are put into a group that does not receive the treatment. Researchers can then compare what happens to those who receive the treatment with what happens to those who do not.

With your consent, ********** was randomly assigned to receive either the care offered in your hospital alone or the hospital care with an added treatment. The RECOVERY trial initially evaluated two treatments in children aged under 18: **methylprednisolone**, a type of steroid that helps to reduce inflammation, and **immunoglobulin**, an antibody treatment that helps the immune system's ability to fight infections.

For some children who needed further treatment, the trial also assessed two treatments for children whose symptoms did not improve initially. The second treatments were **tocilizumab** and **anakinra**, both of which are usually used to reduce inflammation in people with rheumatoid arthritis.

In total, 237 children took part in the trial and the average age of those was about 9.5 years old. The trial researchers looked at how long the children needed to stay in hospital and assessed a range of other factors, including whether or not they needed heart support medicines and measures of levels of inflammation in the body. The trial also assessed the safety of each of the tested treatments by looking at any potential side effects.

Going 'behind the scenes' of the trial

A wide range of different people have played an essential part in making the RECOVERY trial happen. You can learn more about these through a collection of interviews that go 'behind the scenes' of the study on the RECOVERY trial website (recoverytrial.net/case_studies).

Other recent highlights

- On Clinical Trials Day (20 May 2023), we launched a video featuring two members of the trial's Coordinating Centre team; a trial participant, Elaine Bowden; a clinician, Dr Raha West; and the former Government Chief Scientific Adviser, Sir Patrick Vallance.
- The RECOVERY trial has received several prestigious awards, all of which recognise the contribution made by participants, most recently from the Galien Foundation for 'Best Public Sector Innovation' and the Medical Research Council for 'Outstanding Team Impact'.

You can see the video and read more about these highlights in the news section of the RECOVERY website at recoverytrial.net/news. The news section of the website also has an article describing how RECOVERY successfully enabled the

participation of pregnant women, so that we have information about treatments that are suitable for them.

How we are using your child's data

All information about your child and their health is kept private. Data from which your child cannot be recognised may be shared with other research groups who are doing similar research. There is more information about this in the 'For patients in the UK' section of the trial website (recoverytrial.net/patients).

Researchers working on other studies can now apply to access RECOVERY trial data so that they can answer new research questions using data that have already been collected. The researchers must prove that their work will help public health and they will only be provided with the information needed to answer their specific question (and no information that identifies your child). You can find out more about this in an animation in the 'For patients' section of the trial website.

Communicating with us

If you would like to discuss anything in this newsletter, or any other aspect of the study, with a member of the study team you can contact us by phone (0808 164 4060 Monday to Friday between 9am-5pm), email or post (details at the top of this letter). Please quote the participant ID number in any correspondence. If you would prefer to speak to the doctors at your local hospital, we can put you in touch with them.

This letter was sent to you on behalf of RECOVERY by NHS England via APS (an NHS-approved mailing house).

Thank you again for your support in this remarkable effort to save the lives of patients with COVID-19.

Yours sincerely,

Professor Sir Martin Landray and Professor Sir Peter Horby, Chief Investigators

NHDA3_1_T260554_010824\000001\4\4of4\

RECOVERY Central Coordinating Office
Nuffield Department of Population Health
Richard Doll Building, Old Road Campus
Roosevelt Drive, Oxford, OX3 7LF

Tel: 0808 164 4060
Email: recoverytrial@ndph.ox.ac.uk
Website: www.recoverytrial.net

****

00002
000003\324 *

ID Number: **********

Dear parent/guardian of ********** ,

Participation in the RECOVERY trial

On behalf of the University of Oxford and local hospital trial teams, we wish to thank you for agreeing that ********** could take part in the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial. This is the largest clinical trial in the world to find effective treatments against the effects of COVID-19 for patients in hospital.

We are writing to update you on the results of the part of the trial that aimed to find an effective treatment for children in hospital with a condition called paediatric inflammatory multisystem syndrome (PIMS) because of a COVID-19 infection. PIMS causes inflammation in the body when the immune system fights off the virus but then overreacts to affect other parts of the body.

You can read more about the the trial and the treatments tested on the second page of this letter and on the RECOVERY website at www.recoverytrial.net/news.

Results of the trial

Your child's participation in RECOVERY has helped us to find out that:

- Initial treatment with methylprednisolone is effective at reducing the length of time that children with PIMS need to spend in hospital;
- If symptoms do not improve, tocilizumab is an effective treatment for reducing the length of time that children with PIMS need to spend in hospital;
- Immunoglobulin was not an effective treatment for PIMS;
- Some children who were given methylprednisolone and tocilizumab needed more heart support medicines than children not given these added treatments, but all the treatments were found to be safe for children.

NHDA3_1_T260554_010824\000003\9\1of4\

IRAS 281712 REC Ref 20/EE/0101 The study was funded by UK Research and Innovation, the National Institute for Health and Care Research, and Wellcome. It is registered at ISRCTN50189673.

We were not able to find out if anakinra was effective because the number of children being admitted with PIMS became very small.

The trial 'in a nutshell'

The only way to find out whether or not a potential treatment works is to assess it in a randomised controlled trial. This means that a number of similar people are randomly selected to either receive a treatment or are put into a group that does not receive the treatment. Researchers can then compare what happens to those who receive the treatment with what happens to those who do not.

With your consent, ********** was randomly assigned to receive either the care offered in your hospital alone or the hospital care with an added treatment. The RECOVERY trial initially evaluated two treatments in children aged under 18: **methylprednisolone**, a type of steroid that helps to reduce inflammation, and **immunoglobulin**, an antibody treatment that helps the immune system's ability to fight infections.

For some children who needed further treatment, the trial also assessed two treatments for children whose symptoms did not improve initially. The second treatments were **tocilizumab** and **anakinra**, both of which are usually used to reduce inflammation in people with rheumatoid arthritis.

In total, 237 children took part in the trial and the average age of those was about 9.5 years old. The trial researchers looked at how long the children needed to stay in hospital and assessed a range of other factors, including whether or not they needed heart support medicines and measures of levels of inflammation in the body. The trial also assessed the safety of each of the tested treatments by looking at any potential side effects.

Going 'behind the scenes' of the trial

A wide range of different people have played an essential part in making the RECOVERY trial happen. You can learn more about these through a collection of interviews that go 'behind the scenes' of the study on the RECOVERY trial website (recoverytrial.net/case_studies).

Other recent highlights

- On Clinical Trials Day (20 May 2023), we launched a video featuring two members of the trial's Coordinating Centre team; a trial participant, Elaine Bowden; a clinician, Dr Raha West; and the former Government Chief Scientific Adviser, Sir Patrick Vallance.
- The RECOVERY trial has received several prestigious awards, all of which recognise the contribution made by participants, most recently from the Galien Foundation for 'Best Public Sector Innovation' and the Medical Research Council for 'Outstanding Team Impact'.

You can see the video and read more about these highlights in the news section of the RECOVERY website at recoverytrial.net/news. The news section of the website also has an article describing how RECOVERY successfully enabled the

participation of pregnant women, so that we have information about treatments that are suitable for them.

How we are using your child's data

All information about your child and their health is kept private. Data from which your child cannot be recognised may be shared with other research groups who are doing similar research. There is more information about this in the 'For patients in the UK' section of the trial website (recoverytrial.net/patients).

Researchers working on other studies can now apply to access RECOVERY trial data so that they can answer new research questions using data that have already been collected. The researchers must prove that their work will help public health and they will only be provided with the information needed to answer their specific question (and no information that identifies your child). You can find out more about this in an animation in the 'For patients' section of the trial website.

Communicating with us

If you would like to discuss anything in this newsletter, or any other aspect of the study, with a member of the study team you can contact us by phone (0808 164 4060 Monday to Friday between 9am-5pm), email or post (details at the top of this letter). Please quote the participant ID number in any correspondence. If you would prefer to speak to the doctors at your local hospital, we can put you in touch with them.

This letter was sent to you on behalf of RECOVERY by NHS England via APS (an NHS-approved mailing house).

Thank you again for your support in this remarkable effort to save the lives of patients with COVID-19.

Yours sincerely,

Professor Sir Martin Landray and Professor Sir Peter Horby, Chief Investigators

OXFORD POPULATION HEALTH

NUFFIELD DEPARTMENT of MEDICINE

UNIVERSITY OF OXFORD

NHDA3_1_T260554_010824\000003\12\4of4\

RECOVERY Central Coordinating Office
Nuffield Department of Population Health
Richard Doll Building, Old Road Campus
Roosevelt Drive, Oxford, OX3 7LF

Tel: 0808 164 4060
Email: recoverytrial@ndph.ox.ac.uk
Website: www.recoverytrial.net

****

****

00003
000004\325 *

ID Number: **********

Dear parent/guardian of ********** ,

Participation in the RECOVERY trial

On behalf of the University of Oxford and local hospital trial teams, we wish to thank you for agreeing that ********** could take part in the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial. This is the largest clinical trial in the world to find effective treatments against the effects of COVID-19 for patients in hospital.

We are writing to update you on the results of the part of the trial that aimed to find an effective treatment for children in hospital with a condition called paediatric inflammatory multisystem syndrome (PIMS) because of a COVID-19 infection. PIMS causes inflammation in the body when the immune system fights off the virus but then overreacts to affect other parts of the body.

You can read more about the the trial and the treatments tested on the second page of this letter and on the RECOVERY website at www.recoverytrial.net/news.

Results of the trial

Your child's participation in RECOVERY has helped us to find out that:

- Initial treatment with methylprednisolone is effective at reducing the length of time that children with PIMS need to spend in hospital;
- If symptoms do not improve, tocilizumab is an effective treatment for reducing the length of time that children with PIMS need to spend in hospital;
- Immunoglobulin was not an effective treatment for PIMS;
- Some children who were given methylprednisolone and tocilizumab needed more heart support medicines than children not given these added treatments, but all the treatments were found to be safe for children.

IRAS 281712 REC Ref 20/EE/0101 The study was funded by UK Research and Innovation, the National Institute for Health and Care Research, and Wellcome. It is registered at ISRCTN50189673.

We were not able to find out if anakinra was effective because the number of children being admitted with PIMS became very small.

The trial 'in a nutshell'

The only way to find out whether or not a potential treatment works is to assess it in a randomised controlled trial. This means that a number of similar people are randomly selected to either receive a treatment or are put into a group that does not receive the treatment. Researchers can then compare what happens to those who receive the treatment with what happens to those who do not.

With your consent, ********** was randomly assigned to receive either the care offered in your hospital alone or the hospital care with an added treatment. The RECOVERY trial initially evaluated two treatments in children aged under 18: **methylprednisolone**, a type of steroid that helps to reduce inflammation, and **immunoglobulin**, an antibody treatment that helps the immune system's ability to fight infections.

For some children who needed further treatment, the trial also assessed two treatments for children whose symptoms did not improve initially. The second treatments were **tocilizumab** and **anakinra**, both of which are usually used to reduce inflammation in people with rheumatoid arthritis.

In total, 237 children took part in the trial and the average age of those was about 9.5 years old. The trial researchers looked at how long the children needed to stay in hospital and assessed a range of other factors, including whether or not they needed heart support medicines and measures of levels of inflammation in the body. The trial also assessed the safety of each of the tested treatments by looking at any potential side effects.

Going 'behind the scenes' of the trial

A wide range of different people have played an essential part in making the RECOVERY trial happen. You can learn more about these through a collection of interviews that go 'behind the scenes' of the study on the RECOVERY trial website (recoverytrial.net/case_studies).

Other recent highlights

- On Clinical Trials Day (20 May 2023), we launched a video featuring two members of the trial's Coordinating Centre team; a trial participant, Elaine Bowden; a clinician, Dr Raha West; and the former Government Chief Scientific Adviser, Sir Patrick Vallance.
- The RECOVERY trial has received several prestigious awards, all of which recognise the contribution made by participants, most recently from the Galien Foundation for 'Best Public Sector Innovation' and the Medical Research Council for 'Outstanding Team Impact'.

You can see the video and read more about these highlights in the news section of the RECOVERY website at recoverytrial.net/news. The news section of the website also has an article describing how RECOVERY successfully enabled the

participation of pregnant women, so that we have information about treatments that are suitable for them.

How we are using your child's data

All information about your child and their health is kept private. Data from which your child cannot be recognised may be shared with other research groups who are doing similar research. There is more information about this in the 'For patients in the UK' section of the trial website (recoverytrial.net/patients).

Researchers working on other studies can now apply to access RECOVERY trial data so that they can answer new research questions using data that have already been collected. The researchers must prove that their work will help public health and they will only be provided with the information needed to answer their specific question (and no information that identifies your child). You can find out more about this in an animation in the 'For patients' section of the trial website.

Communicating with us

If you would like to discuss anything in this newsletter, or any other aspect of the study, with a member of the study team you can contact us by phone (0808 164 4060 Monday to Friday between 9am-5pm), email or post (details at the top of this letter). Please quote the participant ID number in any correspondence. If you would prefer to speak to the doctors at your local hospital, we can put you in touch with them.

This letter was sent to you on behalf of RECOVERY by NHS England via APS (an NHS-approved mailing house).

Thank you again for your support in this remarkable effort to save the lives of patients with COVID-19.

Yours sincerely,

Professor Sir Martin Landray and Professor Sir Peter Horby, Chief Investigators

NHDA3_1_T260554_010824\000004\16\4of4\