

# FIONA'S ADVENTURE

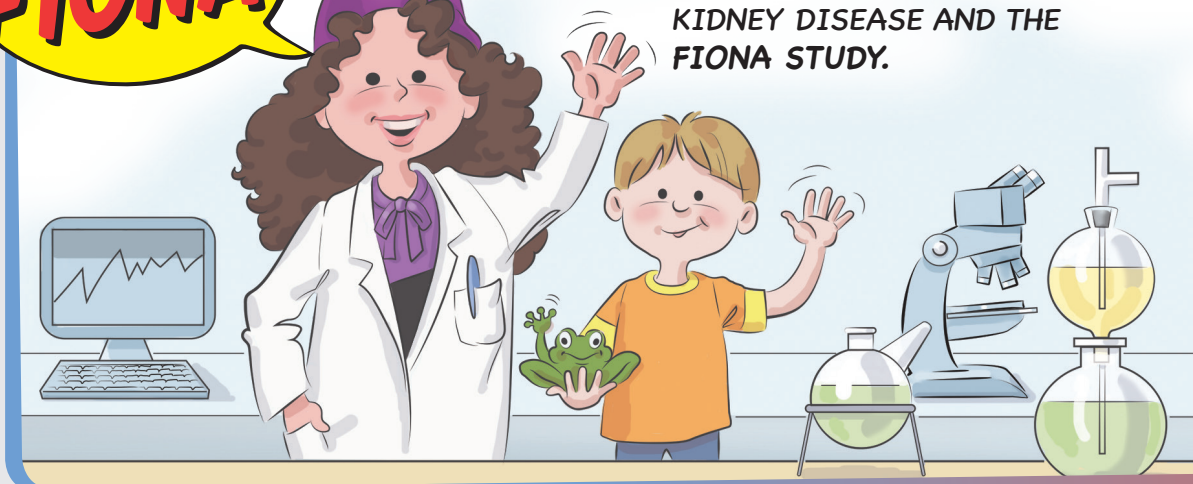
Exploring CKD  
and the  
FIONA Study



19920 FIONA, Child/Pre-teen Booklet, EN, V 2.0, 29JUN22

HI! I AM  
**FIONA**

AND THESE ARE MY  
HELPERS. WE ARE HERE  
TO HELP YOU DISCOVER  
KIDNEY DISEASE AND THE  
**FIONA STUDY.**



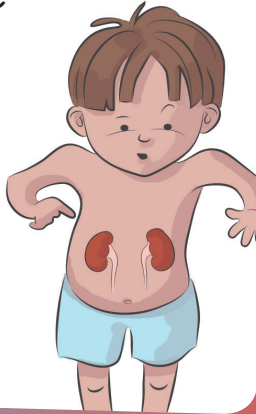
COME JOIN US TO LEARN HOW  
THE KIDNEYS WORK, WHAT  
CHRONIC KIDNEY DISEASE IS  
AND WHAT HAPPENS IN THE  
**FIONA STUDY.**



HI, I'M  
FIONA'S  
ASSISTANT,  
FINNY THE  
FROG!



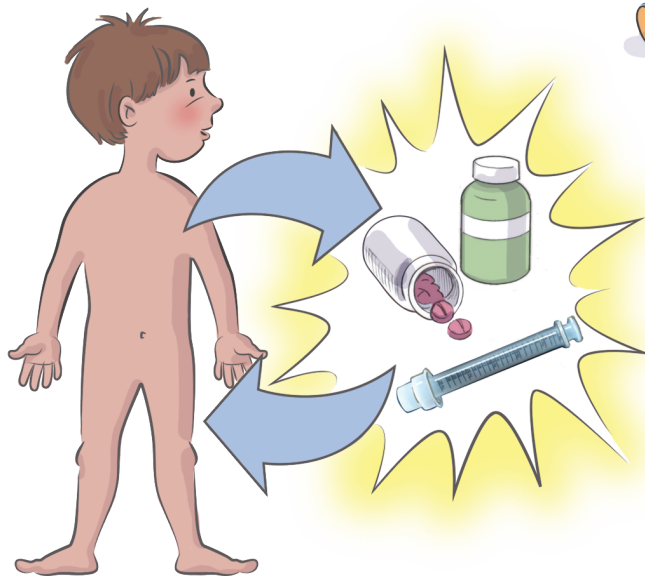
THE STUDY INVOLVES CHILDREN WHO HAVE CHRONIC KIDNEY DISEASE (CKD).



## MESSAGE FOR PARENTS

YOU CAN READ THIS STORY WITH YOUR CHILD. IF YOUR CHILD HAS QUESTIONS, ENCOURAGE HIM/HER TO ASK THE STUDY DOCTOR OR NURSES.

IN THE STUDY, DOCTORS ARE LOOKING AT A STUDY MEDICATION CALLED FINERENONE TO SEE IF IT IS SAFE AND IF IT MAY HELP CHILDREN WITH KIDNEY DISEASE.



## DISCOVER KIDNEYS!



LET'S START BY GETTING TO KNOW KIDNEYS AND WHAT THEY DO.

THE KIDNEYS ARE THE PART OF YOUR BODY THAT MAKES URINE (PEE). THEY HAVE THE SHAPE OF A BIG BEAN.

BEFORE LEAVING YOUR BODY, URINE TRAVELS THROUGH:

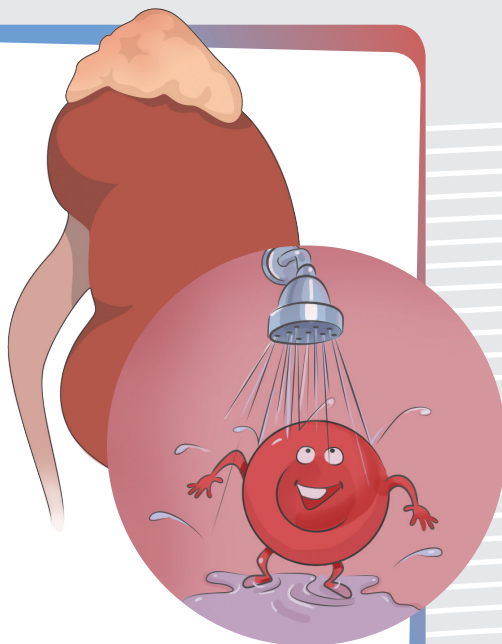


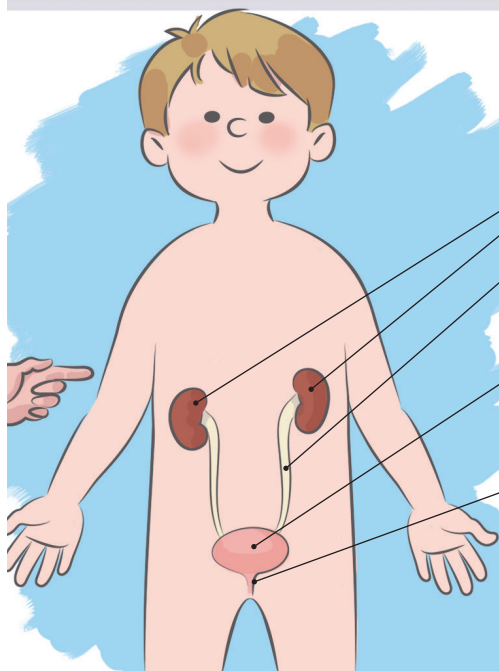
TAKE A LOOK AT THESE TWO IMPORTANT JOBS OF YOUR KIDNEYS:

### NUMBER 1

KIDNEYS CLEAN YOUR BLOOD.

KIDNEYS TAKE STUFF YOUR BODY DOESN'T NEED (WASTE) OUT OF YOUR BLOOD AND PRODUCE PEE TO GET RID OF IT.





## THE PEE PATH

**KIDNEYS** MAKE PEE

**URETERS** (TUBES) CARRY URINE FROM THE KIDNEYS TO THE BLADDER

**BLADDER** (A POUCH) STORES URINE UNTIL YOU ARE READY TO PEE

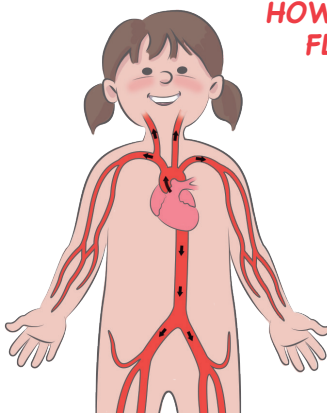
**URETHRA** (A TUBE) CARRIES YOUR PEE FROM THE BLADDER TO OUTSIDE YOUR BODY

## NUMBER 2

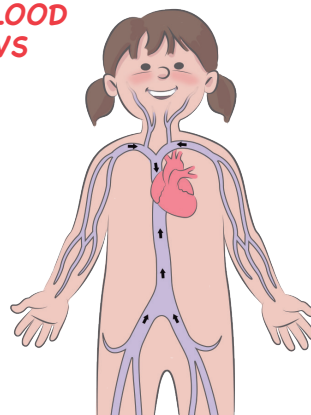
KIDNEYS HELP CONTROL YOUR BLOOD PRESSURE.

BLOOD PRESSURE IS THE FORCE THAT MAKES BLOOD FLOW AROUND THE BODY.

## HOW BLOOD FLOWS



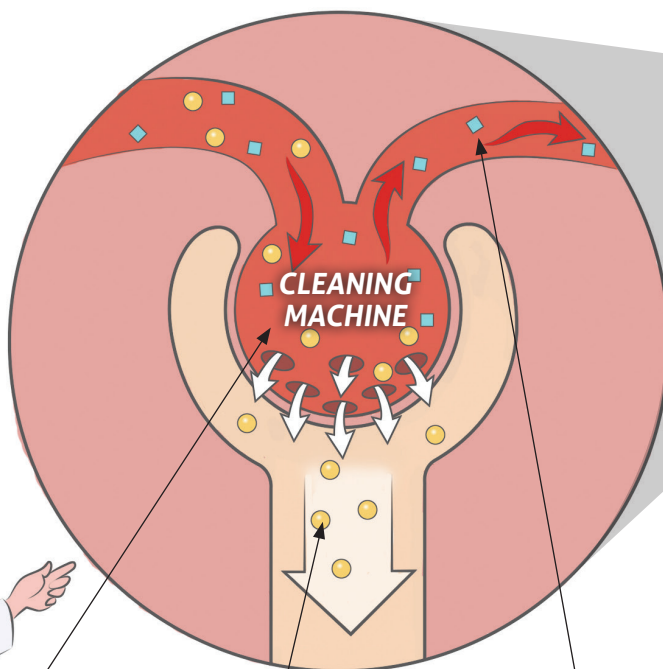
WHEN THE HEART BEATS, IT PUSHES BLOOD THROUGH TUBES CALLED ARTERIES.



WHEN THE HEART RELAXES BETWEEN BEATS, BLOOD RETURNS TO THE HEART THROUGH TUBES CALLED VEINS.

# HOW KIDNEYS WORK

## CLEANING THE BLOOD



1

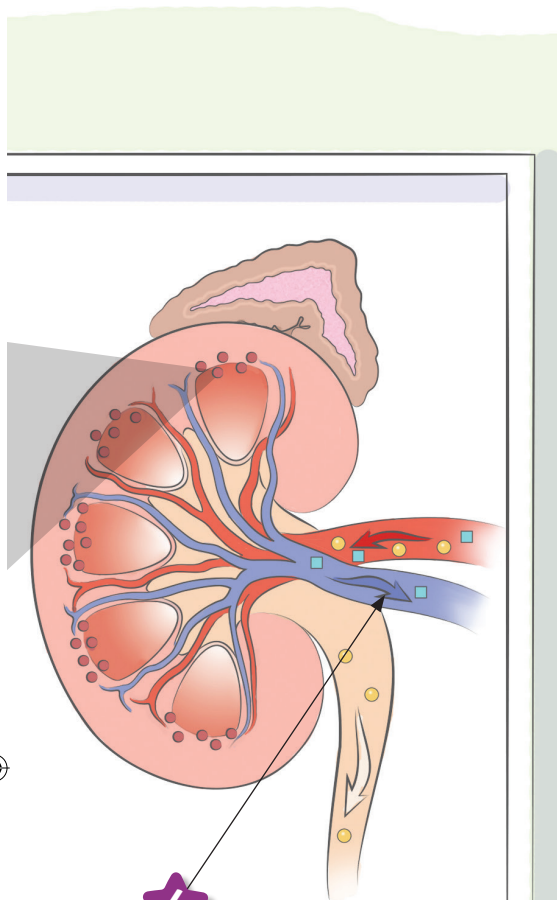
INSIDE THE KIDNEYS BLOOD GOES THROUGH TINY "CLEANING MACHINES."

2

CLEANING MACHINES REMOVE WASTE FROM THE BLOOD AND SEND IT, ALONG WITH EXTRA WATER, INTO TUBES WHERE IT BECOMES URINE.

3

GOOD STUFF YOUR BODY NEEDS, LIKE PROTEIN, STAYS IN THE CLEANED BLOOD.



4

CLEANED  
BLOOD  
RETURNS TO  
THE BODY.

#### LEGEND

Proteins

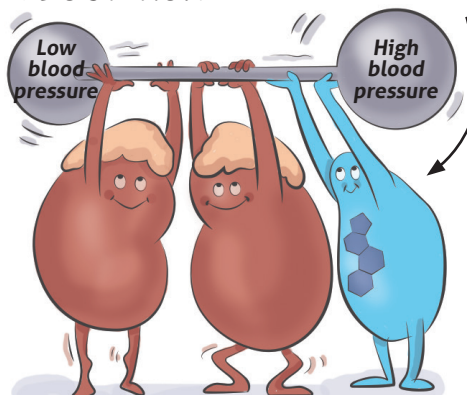


Waste



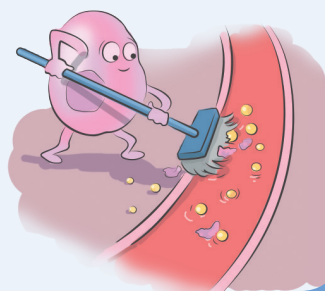
## BALANCING BLOOD PRESSURE

KIDNEYS BALANCE BLOOD PRESSURE TO MAKE SURE BLOOD FLOWS AT THE RIGHT SPEED THROUGH THEIR "CLEANING MACHINES." WHEN BLOOD PRESSURE CHANGES, KIDNEYS TRY TO BRING IT BACK TO THE RIGHT LEVEL. A SPECIAL SUBSTANCE CALLED ALDOSTERONE HELPS THEM.



## ★ WHAT IS "WASTE" AND HOW DOES IT GET INTO THE BLOOD?

THE CELLS THAT MAKE UP YOUR BODY NEED NUTRIENTS (FOOD) TO GROW AND WORK PROPERLY. NOT ALL PARTS OF THE FOOD ARE USED. THE UNUSED FOOD, TOGETHER WITH OLD CELLS THAT HAVE DIED, IS WHAT WE CALL WASTE. CELLS GET RID OF WASTE BY DUMPING IT INTO THE BLOOD.



7

**WHAT  
DAMAGES  
KIDNEYS?**

**LET'S  
DISCOVER  
WHAT CAN  
HURT KIDNEYS**



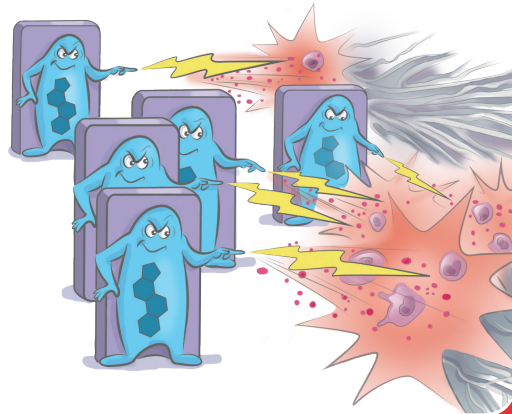
**KIDNEYS MAY BE DAMAGED  
(HURT) BY**

- ✧ **INFECTIONS.** INFECTIONS ARE CAUSED BY TINY LIVING THINGS CALLED GERMS. IF THE INFECTION HAPPENS IN THE KIDNEYS, KIDNEYS CAN GET HURT.
  - ✧ **INFLAMMATION.** INFLAMMATION HAPPENS WHEN YOUR BODY IS TRYING TO FIGHT OFF AN INFECTION, BUT CAN ALSO HAPPEN WITHOUT GERMS. WHEN INFLAMMATION HAPPENS IN THE KIDNEYS AND IS TOO STRONG, KIDNEYS CAN GET HURT.
  - ✧ **HIGH BLOOD PRESSURE.** HIGH BLOOD PRESSURE MAY HAPPEN BECAUSE KIDNEYS ARE NOT BALANCING IT WELL.
  - ✧ **SOMETHING YOU ARE BORN WITH.**
  - ✧ **OR OTHER CONDITIONS.**
- IF YOU HAVE QUESTIONS, TALK WITH YOUR PARENTS OR DOCTOR.**



## TOO MUCH ALDOSTERONE

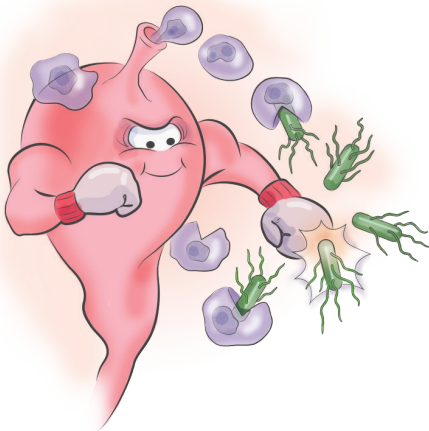
WHEN KIDNEYS ARE SICK, THE BODY MAY PRODUCE TOO MUCH ALDOSTERONE. ALDOSTERONE CAN CAUSE INFLAMMATION AND SCARRING (FIBROSIS) IN THE KIDNEY.



## WHAT ARE INFLAMMATION AND FIBROSIS

USUALLY, INFLAMMATION FIGHTS OFF GERMS AND OTHER BAD GUYS INVADING THE BODY.

FIBROSIS HEALS INJURIES. IT IS THE WAY YOUR BODY CREATES A SCAR IF YOU GET HURT (LIKE WHEN YOU SKIN YOUR KNEE).



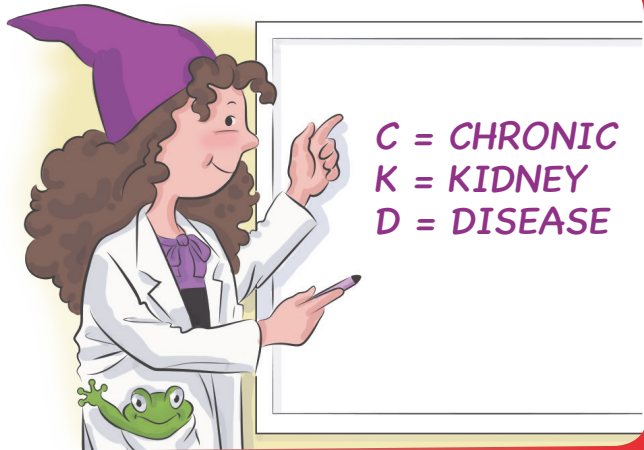
## BUT...

...IF INFLAMMATION AND SCARS HAPPEN INSIDE THE KIDNEYS' "CLEANING MACHINES," THE KIDNEYS MAY HAVE A HARD TIME CLEANING THE BLOOD.

## WHAT IS CKD?

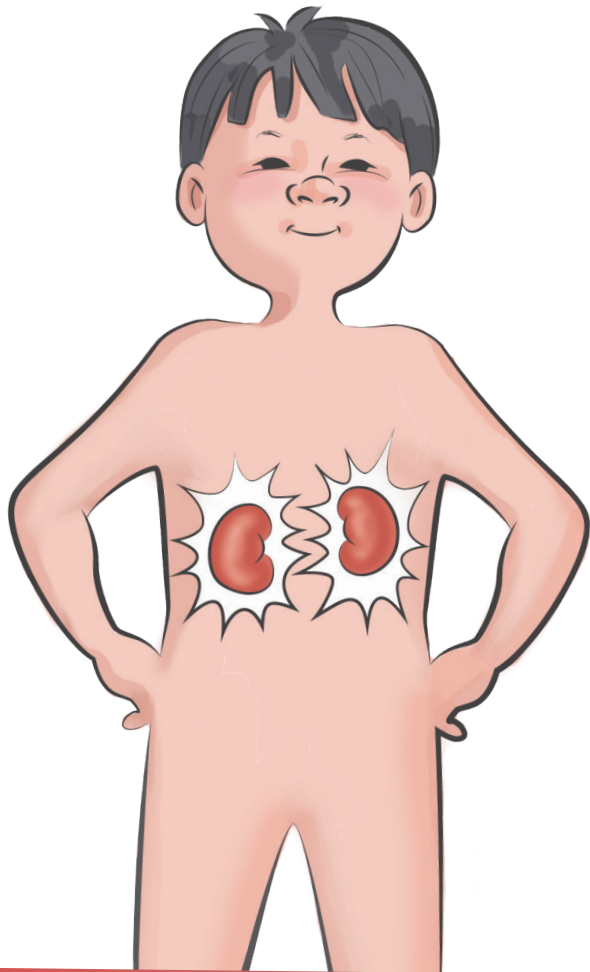
CKD IS THE SHORT NAME FOR CHRONIC KIDNEY DISEASE.

CHRONIC MEANS HAVING A DISEASE FOR A LONG TIME.



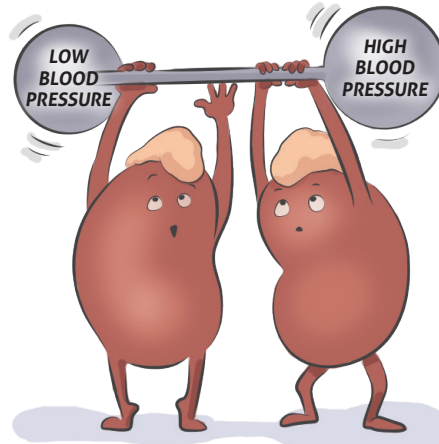
HAVING CKD MEANS THE KIDNEYS' "CLEANING MACHINES" ARE DAMAGED AND MAY NOT BE WORKING SO WELL.

WASTE MAY BE BUILDING UP IN THE BODY.



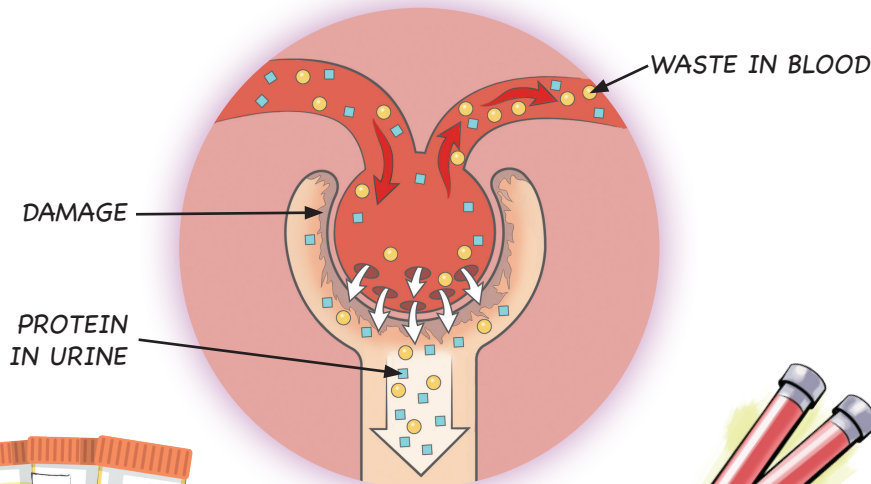
## BLOOD PRESSURE MAY BE TOO HIGH

WHEN KIDNEYS ARE  
DAMAGED, THEY  
MAY NOT BE ABLE  
TO BALANCE BLOOD  
PRESSURE.  
BLOOD PRESSURE MAY  
GO UP.



THE GOOD STUFF, LIKE  
PROTEINS THAT THE BODY  
NEEDS, MAY LEAK INTO  
THE URINE.

WASTE MAY STAY IN  
YOUR BLOOD.



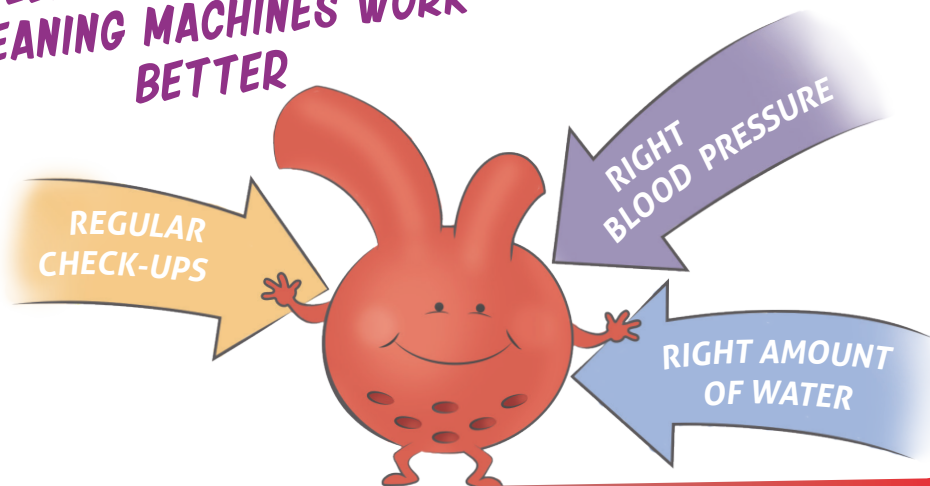
DOCTORS WILL ASK YOU TO BRING  
SOME SAMPLES OF YOUR URINE (IN  
CUPS) TO THE HOSPITAL SO THEY CAN  
CHECK IF IT HAS PROTEINS IN IT.



DOCTORS WILL ALSO  
CHECK YOUR BLOOD  
TO SEE IF THEY FIND  
A WASTE CALLED  
CREATININE.



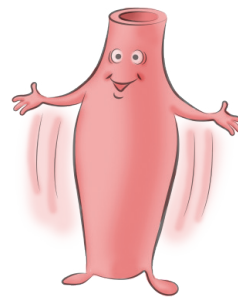
## HELPING THE KIDNEYS' CLEANING MACHINES WORK BETTER



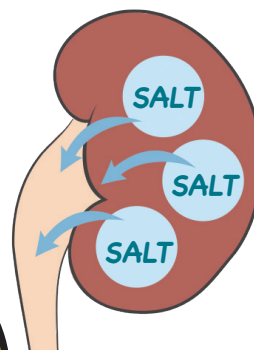
### BLOOD PRESSURE DRUGS

DRUGS WORK IN DIFFERENT WAYS TO HELP LOWER BLOOD PRESSURE.

THEY CAN HELP THE TUBES THAT CARRY BLOOD AROUND YOUR BODY (BLOOD VESSEL) RELAX AND EXPAND. IF BLOOD VESSELS RELAX, BLOOD PRESSURE GOES DOWN.

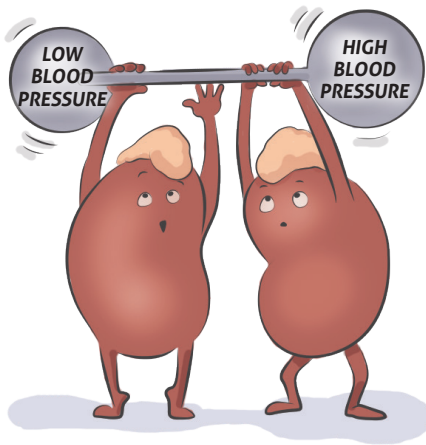


SOME DRUGS CALLED DIURETICS (OR WATER PILLS) HELP YOUR KIDNEYS GET RID OF SALT AND TOO MUCH WATER. SALT AND WATER END UP IN URINE. LESS WATER STAYS IN THE BLOOD AND PRESSURE GOES DOWN.



SOME DRUGS ALSO HELP KIDNEYS KEEP THE GOOD STUFF (PROTEINS) INSIDE YOUR BODY.

## KEEPING BLOOD PRESSURE BALANCED



KIDNEYS ARE ALWAYS TRYING TO BALANCE BLOOD PRESSURE. HELPING THEM IN THIS JOB IS IMPORTANT TO PROTECT THEM. IF BLOOD PRESSURE IS HIGH, THE KIDNEYS' CLEANING MACHINES CAN GET DAMAGED. DOCTORS MAY CHECK YOUR BLOOD PRESSURE OFTEN AND ASK YOU TO TAKE DRUGS FOR BLOOD PRESSURE.

## HOW IS BLOOD PRESSURE MEASURED?

- ☆ THE DOCTOR OR NURSE PUTS A CUFF ON YOUR ARM.
- ☆ THE CUFF IS FILLED WITH AIR BY A SPECIAL MACHINE.
- ☆ THE MACHINE MEASURES BLOOD PRESSURE, WHILE SLOWLY LETTING THE AIR OUT OF THE CUFF.



## DRINKING WATER



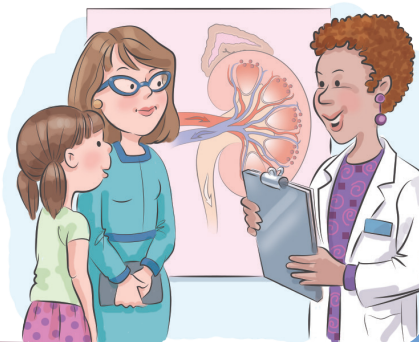
TO WORK WELL YOUR KIDNEYS NEED THE RIGHT AMOUNT OF WATER.

MAKE SURE YOU FOLLOW YOUR DOCTOR'S INSTRUCTIONS, AND DRINK AS MUCH WATER AS YOU SHOULD. THIS IS ESPECIALLY IMPORTANT IN HOT WEATHER, WHILE EXERCISING AND IF YOU DON'T FEEL WELL.



## DISCOVER THE FIONA STUDY!

YOUR STUDY DOCTOR WILL ASK YOU AND YOUR PARENTS IF YOU WOULD LIKE TO JOIN THE FIONA STUDY.

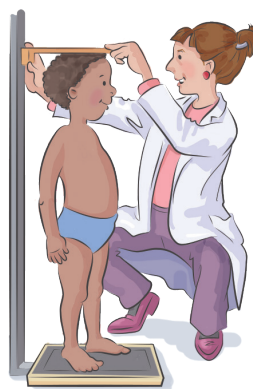


IF YOU DECIDE TO TAKE PART IN THE FIONA STUDY, YOU WILL GO TO THE HOSPITAL OR THE DOCTOR'S OFFICE FOR STUDY VISITS.

THERE YOU WILL MEET THE STUDY DOCTOR AND NURSES.



AT STUDY VISITS, THE STUDY DOCTOR WILL CHECK YOU AND MAY TAKE YOUR TEMPERATURE, MEASURE YOUR HEIGHT AND WEIGHT, ALONG WITH YOUR HEARTBEAT AND BLOOD PRESSURE



...AND TAKE SOME OF YOUR BLOOD.



ON MOST VISITS, YOU WILL ALSO HAVE TO BRING TO THE DOCTOR SOME OF THE PEE YOU MAKE WHEN YOU WAKE UP IN THE MORNING.



TO DECIDE WHETHER YOU WOULD LIKE TO TAKE PART IN THE FIONA STUDY, LOOK AT THE NEXT PAGES. THEY WILL HELP YOU UNDERSTAND WHAT YOUR ROLE IN THE STUDY WILL BE.



DOCTORS WILL CHECK YOU TO MAKE SURE YOU CAN TAKE THE STUDY MEDICATION. THE STUDY DOCTOR WILL ASK YOU AND YOUR PARENTS ABOUT YOUR HEALTH, INCLUDING DRUGS YOU TAKE AND ILLNESSES YOU HAVE HAD.

IF YOU HAVE QUESTIONS, YOU CAN SHARE THEM WITH YOUR PARENTS AND WITH THE STUDY DOCTOR.



REMEMBER THAT YOU ARE NOT ALONE. THERE ARE OTHER CHILDREN WHO HAVE CKD AND ARE BEING INVITED TO THE FIONA STUDY. THEY MAY LIVE IN OTHER CITIES OR OTHER COUNTRIES AROUND THE WORLD.

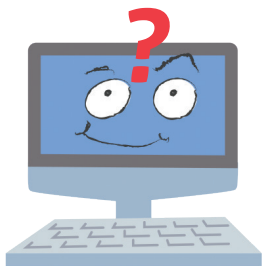
## WHAT HAPPENS IN THE FIONA STUDY?

DURING THE FIONA STUDY, IF ALL THE FIRST CHECKS ARE FINE, YOU WILL TAKE THE STUDY MEDICATION OR THE PLACEBO. KEEP READING TO LEARN MORE.



A COMPUTER WILL DECIDE WHETHER YOU WILL TAKE THE STUDY MEDICATION OR THE PLACEBO. THE PLACEBO IS A PILL OR LIQUID THAT LOOKS LIKE THE STUDY MEDICATION BUT HAS NO MEDICINE IN IT.

NEITHER YOU NOR YOUR DOCTOR WILL KNOW IF YOU WILL BE TAKING THE STUDY MEDICATION OR THE PLACEBO. BUT THE STUDY DOCTOR CAN FIND OUT IN CASE OF EMERGENCY.



## WHAT IS THE STUDY MEDICATION?

THE STUDY MEDICATION BLOCKS THE ACTION OF ALDOSTERONE (FIND OUT ABOUT ALDOSTERONE ON PAGE 9).

THE STUDY MEDICATION IS TAKEN BY MOUTH, ONCE A DAY, AS A PILL OR A LIQUID.



A PILL WITH WATER



OR A LIQUID FROM A SYRINGE

DO NOT MIX IT INTO FOOD!

## STUDY VISITS

YOU WILL VISIT THE HOSPITAL OR THE DOCTOR'S OFFICE ABOUT 10 TIMES OVER A PERIOD OF ABOUT 10 MONTHS.

YOU MAY HAVE TO MISS SOME DAYS OF SCHOOL.



## GIVING BLOOD SAMPLES

TESTING BLOOD IS AN IMPORTANT PART OF THE FIONA STUDY. THE TESTS GIVE YOUR DOCTORS INFORMATION ON HOW THE STUDY MEDICATION WORKS IN YOUR BODY.

YOUR BLOOD WILL BE TAKEN THROUGH A SMALL NEEDLE IN YOUR ARM.



YOUR BLOOD SAMPLE WILL BE SENT TO A LABORATORY FOR TESTING.



SCIENTISTS WILL LOOK AT THE RESULTS OF ALL CHILDREN TAKING PART IN THE FIONA STUDY...



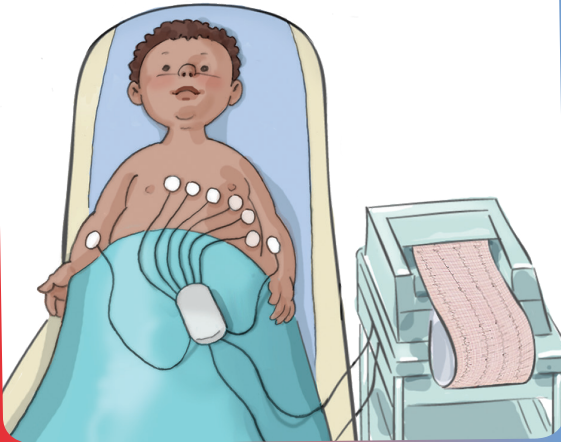
...AND WILL FIND OUT IF THE STUDY MEDICATION IS SAFE AND IF IT HELPS CHILDREN WITH CKD.

## WHAT HAPPENS IN THE FIONA STUDY?

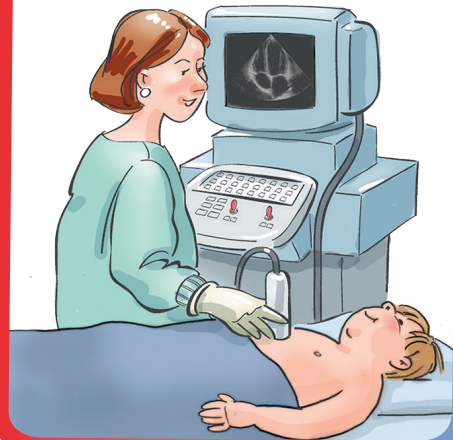
### OTHER TESTS



THE STUDY DOCTORS WILL CHECK YOUR HEART WITH AN EXAM CALLED ECG (ELECTROCARDIOGRAM). THE ECG RECORDS YOUR HEART'S RHYTHM. DOCTORS WILL PLACE STICKERS ON YOUR SKIN AND YOU WON'T FEEL ANY PAIN.



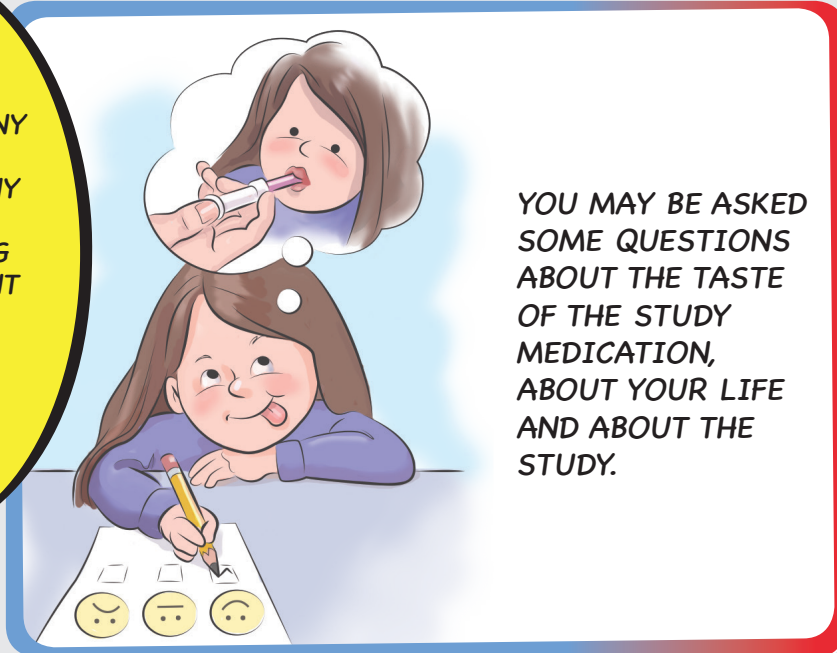
WITH AN EXAM CALLED ECHOCARDIOGRAM (HEART ULTRASOUND), THE STUDY DOCTORS WILL LOOK AT THE SHAPE OF YOUR HEART AND HOW WELL IT IS WORKING.



IF YOU ARE A GIRL...

...AND IF YOU HAVE HAD YOUR FIRST PERIOD, YOUR STUDY DOCTOR MAY TELL YOU ABOUT SOME BLOOD OR URINE TESTS YOU MAY HAVE TO DO.

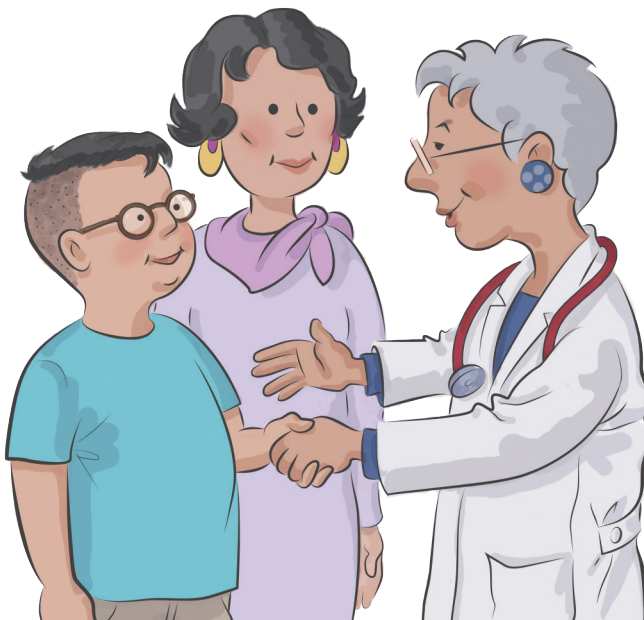
**REMEMBER!**  
DO NOT EAT ANY  
GRAPEFRUIT  
NOR DRINK ANY  
GRAPEFRUIT  
JUICE DURING  
THE TREATMENT  
PERIOD.



**YOU MAY BE ASKED  
SOME QUESTIONS  
ABOUT THE TASTE  
OF THE STUDY  
MEDICATION,  
ABOUT YOUR LIFE  
AND ABOUT THE  
STUDY.**

## **FOLLOW UP**

**YOUR FIONA  
STUDY EXPERIENCE  
WILL END WITH A  
FOLLOW-UP VISIT  
TO CHECK ON YOUR  
HEALTH.  
YOU MAY ALSO  
BE OFFERED THE  
POSSIBILITY TO  
TAKE PART IN  
ANOTHER STUDY  
CALLED FIONA OLE.**



## FIONA SUPPORTERS

STUDY DOCTORS AND NURSES AND KIDNEY EXPERTS WILL SUPPORT YOU ALONG THE FIONA STUDY PATH. YOUR STUDY DOCTOR WILL ALWAYS BE AVAILABLE FOR YOU.

YOU AND YOUR PARENTS CAN CALL HIM OR HER ANY TIME IF YOU HAVE QUESTIONS.



TOGETHER WITH THE FRIENDLY STUDY TEAM, SOMEONE YOU KNOW AND TRUST, LIKE YOUR PARENTS, WILL ALWAYS BE WITH YOU.



A GROUP OF PEOPLE WHO ARE EXPERTS IN TREATING CHILDREN WITH CKD, WILL OFTEN MEET TO TALK ABOUT THE FIONA STUDY. THEIR JOB IS TO MAKE SURE CHILDREN ARE AS SAFE AS POSSIBLE WHILE ON THE FIONA STUDY.



**NOW THAT YOU LEARNED MORE ABOUT CKD, YOU  
KNOW YOU HAVE A VERY IMPORTANT GOAL:  
PROTECT YOUR KIDNEYS!**



**IF YOU JOIN THE  
FIONA STUDY, YOU MAY  
HELP DOCTORS BETTER  
UNDERSTAND HOW THE  
STUDY MEDICATION  
WORKS IN CHILDREN.  
THIS CAN HELP OUT  
OTHER CHILDREN WHO  
HAVE CKD.**



**YOU CAN  
USE THIS PAGE  
TO WRITE DOWN  
YOUR QUESTIONS.  
ASK YOUR  
PARENTS IF YOU  
NEED HELP.**

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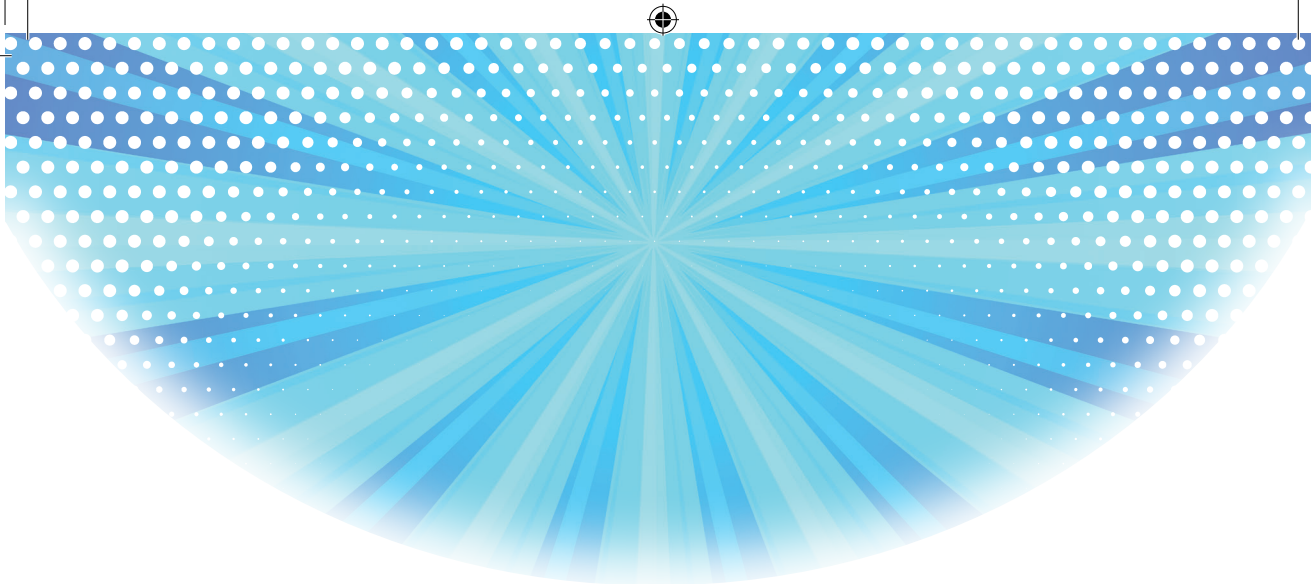
# IMPORTANT!

IF YOU DECIDE TO PARTICIPATE IN THE FIONA STUDY, REMEMBER TO TELL YOUR PARENTS AND CALL THE STUDY DOCTOR IF YOU FEEL UNWELL:

- ☆ TIRED
- ☆ PAIN IN YOUR MUSCLES
- ☆ NUMBNESS (A STRANGE FEELING) IN YOUR HANDS OR LIPS
- ☆ CONFUSED
- ☆ SICK TO THE STOMACH
- ☆ STRANGE HEART BEATS IN YOUR CHEST
- ☆ OR, ANY DIFFERENT OR NEW PAIN OR FEELING

THE STUDY DOCTOR AND THE STUDY STAFF WILL BE THERE TO HELP YOU FEEL BETTER.





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